No. 98-1768-CFX Title: Buckman Company, Petitioner
v.
Plaintiffs' Legal Committee

Docketed: May 4, 1999 Court: United States Court of Appeals for the Third Circuit

Entry	Date	Proceedings and Orders
	May 3 1999	Petition for writ of certiorari filed. (Response due June 3, 1999)
	Jun 1 1999	Brief of respondent Plaintiffs' Legal Committee in opposition filed.
	Jun 2 1999	Motion of Medical Device Manufacturers Association for leave to file a brief as amicus curiae filed.
	Jun 2 1999	Motion of Danek Medical, Inc. for leave to file a brief as amicus curiae filed.
	Jun 2 1999	Motion of Product Liability Advisory Council, Inc. for leave to file a brief as amicus curiae filed.
	Jun 3 1999	Motion of Pharmceutical Research and Manufacturers of America for leave to file a brief as amicus curiae filed.
	Jun 8 1999	Opposition of respondent to motion of Danek Medical, Inc. for leave to file a brief as amicus curiae filed.
	Jun 10 1999	Opposition of respondent to motion of Pharmaceutical Research and Manufacturers of America for leave to file a brief as amicus curiae filed.
	Jun 10 1999	Opposition of respondent to motion of Product Liability Advisory Council, Inc. for leave to file a brief as amicus curiae filed.
	Jun 10 1999	Opposition of respondent to motion of Medical Device Manufacturers Association for leave to file a brief as amicus curiae filed.
	Jun 16 1999	DISTRIBUTED for Conference of September 27, 1999
	Jun 16 1999	Reply brief of petitioner Buckman Company filed.
	Oct 4 1999	The Solicitor General is invited to file a brief in this case expressing the views of the United States.
	Jun 7 2000	Brief amicus curiae of United States filed.
	Jun 13 2000	REDISTRIBUTED for Conference of June 28, 2000
	Jun 29 2000	Motion of Medical Device Manufacturers Association for leave to file a brief as amicus curiae GRANTED.
	Jun 29 2000	Motion of Danek Medical, Inc. for leave to file a brief as amicus curiae GRANTED.
	Jun 29 2000	Motion of Product Liability Advisory Council, Inc. for leave to file a brief as amicus curiae GRANTED.
	Jun 29 2000	Motion of Pharmceutical Research and Manufacturers of America for leave to file a brief as amicus curiae GRANTED.
	Jun 29 2000	Petition GRANTED. limited to the following question: Whether federal law preempts state-law tort claims alleging fraud on the Food and Drug Administration during the regulatory process for marketing clearance applicable to certain medical devices. SET FOR ARGUMENT December 4, 2000.

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No. 98-1768-CFX

Entry	Date	Proceedings and Orders
	Aug 8 2000	Order extending time to file petitioners's brief on the merits to and including September 13, 2000.
	Sep 11 2000	Blanket consent to the filing of amicus briefs in support of either party received from counsel for the petitioner and counsel for the respondent.
	Sep 13 2000	Brief of petitioner Buckman Company filed.
	Sep 13 2000	Brief amicus curiae of Product Liability Advisory Council, Inc. filed.
	Sep 13 2000	Brief amicus curiae of Washington Legal Foundation filed.
	Sep 13 2000	Brief amicus curiae of Medical Device Manufacturers Association filed.
	Sep 13 2000	Brief amicus curiae of Medtronic Sofamor Danek, Inc. filed.
	Sep 13 2000	Joint appendix filed.
	Sep 13 2000	Brief amicus curiae of Pharmceutical Research and Manufacturers of America filed.
	Sep 13 2000	Brief amicus curiae of United States filed.
	Sep 28 2000	Order extending time to file respondent's brief on the merits. Respondent's brief must be filed with the Clerkand served upon opposing counsel on or before 3 p.m., Monday, October 23, 2000. Rule 29.2 does not apply.
	Oct 18 2000	Record filed.
	Oct 23 2000	Brief of respondent Plaintiffs'Legal Committee filed.
	Oct 23 2000	Brief amicus curiae of Association of Trial Lawyers of America filed.
	Oct 23 2000	Brief amicus curiae of Public Citizen filed.
	Oct 24 2000	CIRCULATED.
	Nov 3 2000	Motion of the Solicitor General for leave to participate in oral argument as amicus curiae and for divided argument filed.
	Nov 9 2000	Motion of Solicitor General for leave to participate in oral argument as amicus curiae and for divided argumentDISTRIBUTED.
	Nov 13 2000	Motion of the Solicitor General for leave to participate in oral argument as amicus curiae and for divided argument GRANTED.
	Nov 21 2000	Reply brief of petitioner Buckman Company filed.
	Dec 4 2000	ARGUED.

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Supreme Court, U.S.
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No. 98-

In the Supreme Court of the United States

OCTOBER TERM, 1998

THE BUCKMAN COMPANY,

Petitioner,

v.

PLAINTIFFS' LEGAL COMMITTEE,

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Third Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. Whether a state tort claim collaterally attacking a decision of the Food and Drug Administration to permit the marketing of a medical device on the ground that approval was obtained though a "fraud on the agency" is expressly or impliedly preempted by the Medical Device Amendments to the Federal Food, Drug and Cosmetic Act.

2. Whether the Medical Device Amendments, which expressly preempt "any" state requirement that "relates to the safety or effectiveness" of a device and is "different from, or in addition to" a federal requirement (21 U.S.C. § 360k(a)), exclude state requirements that are imposed through tort laws of general applicability.

RULE 29.6 STATEMENT

Pursuant to Supreme Court Rule 29.6, petitioner states that it has no parent companies or nonwholly owned subsidiaries.

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TABLE OF AUTHORITIES — CONTINUED

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Mitchell v. *Collagen Corp.*, 126 F.3d 902 (1997), cert. denied, 118 S. Ct. 1300 (1998) . . . . . *passim*

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TABLE OF AUTHORITIES — CONTINUED

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Weiland v. *Telectronics Pacing Sys., Inc.*, 704 N.E.2d 854 (Ill. App. Ct. 1998), appeal allowed (Ill. Mar. 31, 1999) (Table, No. 86903) . . 23

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OPINIONS BELOW

The opinion of the court of appeals (App., *infra*, 1a-32a) is reported at 159 F.3d 817. The opinion of the district court (App., *infra*, 33a-44a), which was incorporated in the order granting petitioner's motion for dismissal (App., *infra*, 45a), is unreported. The original opinion of the district court (App., *infra*, 46a-53a) is unreported.

JURISDICTION

The court of appeals' judgment was entered on November 19, 1998. A timely petition for rehearing was denied on February 3, 1999 (App., *infra*, 57a-58a). The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

The Supremacy Clause of the Constitution provides in relevant part: "[T]he Laws of the United States * * * shall be the supreme Law of the Land * * * any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. CONST. art. VI, cl. 2.

The relevant provision of the Medical Device Amendments, 21 U.S.C. § 360k, is reproduced at App., *infra*, 59a.

STATEMENT

This case raises important, recurring questions relating to the preemptive scope of the Medical Device Amendments of 1976 (MDA), 21 U.S.C. § 360k(a), the meaning of this Court's fractured decision in *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996), and the validity of efforts by litigants to circumvent Congress's express preemption commands through state tort claims asserting that federal administrative determinations should be disregarded because they were the product of "fraud on the agency."

In 1976, Congress greatly expanded the authority of the

Food and Drug Administration (FDA) to regulate medical devices, such as heart pacemakers and orthopedic bone screws, by enacting the MDA. To protect the uniformity of the federal regulatory scheme, the MDA provides that no State may impose any requirement relating to the safety or effectiveness of a medical device that "is different from, or in addition to, any requirement applicable * * * to the device" under federal law. 21 U.S.C. § 360k(a). In *Medtronic*, this Court interpreted the MDA's preemption provision, but that opinion has engendered widespread conflict and confusion in the lower courts, as reflected in the decision below.

The first conflict, which the court below expressly recognized, concerns whether the MDA preempts a state tort claim that a manufacturer "defrauded" the FDA by making misrepresentations during the regulatory approval process. In contrast to the Seventh and Eleventh Circuits, the Third Circuit has held that so-called "fraud on the agency" claims are not prohibited attempts under state law to second-guess the determinations of a federal agency. If permitted, "fraud on the agency" claims would allow state judges and lay jurors to create havoc with the federal regulatory scheme by deciding that an administrative agency's decision should be ignored even where the agency itself, in full possession of the relevant facts, does not believe that any fraud was committed. As Judge Cowen stated in dissent (App., *infra*, 32a), "[i]t seems very unlikely that Congress intended a state cause of action to intrude so much both in the enforcement of the FDCA's regulatory scheme and in the severity of the penalties attached to a violation."

The second conflict concerns an even more fundamental question raised but not settled by *Medtronic*: whether the MDA can ever preempt a state tort claim of general applicability. The Third Circuit, like the Tenth Circuit, has held that the MDA was not meant to preempt such claims, but the Fourth, Sixth, Seventh and Ninth Circuits have reached the

opposite conclusion. Both of these issues merit further review.

A. The Regulatory Structure of the Medical Device Amendments

The MDA divides medical devices into three classifications based on the possible risks of harm. Devices such as tongue depressors, which present little likelihood of illness or injury, are designated as Class I and subjected only to minimal regulation, or "general controls." 21 U.S.C. § 360c(a)(1)(A). Potentially more dangerous devices, such as tampons, which are classified as Class II, face increased regulation but can still be marketed without FDA approval. *Id.* § 360c(a)(1)(B). The FDA designates as Class III those devices that are "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health" or which "present[] a potential unreasonable risk of illness or injury." *Id.* § 360c(a)(1)(C). All post-1976 devices, including the orthopedic bone screws at issue here,[1] are initially automatically considered Class III devices and cannot be marketed without FDA clearance or approval. *Id.* §§ 360e(a), 360c(f)(1).

Manufacturers may obtain permission to market Class III devices in either of two ways. First, the FDA may grant approval after a thorough premarket approval (PMA) process, in which the manufacturer must present the FDA with "reasonable assurance" that the device is safe and effective. 21 U.S.C. § 360e. Second, to allow competition with "grandfathered" devices that were on the market in 1976 when the MDA took effect, the FDA may permit marketing of a new device if the manufacturer submits a "premarket

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[1] After these suits were filed, many of the bone screws challenged by plaintiffs were reclassified as Class II devices as part of pedicle screw systems. 63 Fed. Reg. 40025, 40027 (1998).

notification" showing that the device is "substantially equivalent" to a pre-1976 device. *Id.* §§ 360e(b)(1)(B), 360(k), 360c(f)(1)(B). The "premarket notification" route is often referred to as the "510(k)" process, after the section number in the original act. See *Medtronic*, 518 U.S. at 478.

The FDA has established detailed requirements for manufacturers' Section 510(k) notifications. See 21 C.F.R. § 807.87 (1986).[2] Manufacturers must submit "[p]roposed labels, labeling, and advertisement sufficient to describe the device, its intended use, and the directions for its use"; supporting information; comparisons with currently distributed devices; and data showing the effect on safety and effectiveness of any significant changes from the pre-1976 device. *Ibid.*

Once a device has been approved for marketing under Section 510(k), the manufacturer may not market or promote it for uses other than those specified in the FDA clearance.[3] However, physicians remain free under federal law to employ the device for any purpose, including so-called "off-label uses." See *Ortho Pharm. Corp.* v. *Cosprophar, Inc.*, 32 F.3d 690, 692 (2d Cir. 1994). Not only has the FDA recognized the existence of off-label uses (which, as part of the practice of medicine, it cannot regulate, see 21 U.S.C. § 396); it has also acknowledged that "'unapproved' or, more precisely, 'un-labeled' uses may be appropriate and rational in certain circumstances, and may, in fact reflect approaches

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[2] These requirements were expanded by the Safe Medical Devices Act of 1990, Pub. L. No. 101-629, 104 Stat. 4511 (1990), to require more detailed descriptions of the design, materials, properties, functioning, and scientific basis of the device. See 21 C.F.R. §§ 807.87, 807.92, 807.93 (1998).

[3] What constitutes marketing or promotion remains uncertain. See *Washington Legal Found.* v. *Friedman*, 36 F. Supp. 2d 16, 19 (D.D.C. 1999).

* * * that have been extensively reported in medical literature." FDA DRUG BULL. 12:4-5 (1982) (quoted in 59 Fed. Reg. 59820, 59821 (1994)). Off-label uses of devices have "traditionally been regulated by the hospitals in which the physicians practice and not by the FDA." FOOD & DRUG ADMIN., UPDATE ON PEDICLE SCREWS (1993) (quoted in Beck & Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 FOOD & DRUG L.J. 71, 77 (1998)).

B. The FDA's Clearance of the Bone Screws

Petitioner The Buckman Company (Buckman) is a regulatory consultant for medical device manufacturers, helping them navigate FDA procedures, plan regulatory strategy, and monitor clinical trials. In 1984, AcroMed Corporation hired Buckman as its liaison with the FDA to attempt to obtain marketing clearance for its devices. See App., *infra*, 4a-5a.

In September 1984, Buckman, on behalf of AcroMed, applied for Section 510(k) marketing clearance for an orthopedic bone screw device, the Variable Screw Placement Spinal Plate Fixation System (VSP).[4] This application stated that AcroMed intended to market the VSP as a pedicle screw for use in spinal surgery. App., *infra*, 5a. The FDA rejected the application, finding that the VSP was a Class III device not substantially equivalent to any pre-1976 devices. A year later, AcroMed, through Buckman, submitted a second Section 510(k) application for the VSP, again indicating that the device would be labeled as a pedicle screw. The FDA rejected this application as well. *Ibid.*

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[4] Also at issue is AcroMed's ISOLA Spine Fixation System, for which Buckman obtained Section 510(k) clearance in 1986. Like the Third Circuit, "our discussion of the VSP system applies with equal force to the ISOLA system." App., *infra*, 5a n.2.

In December 1985, following a meeting with FDA officials, AcroMed and Buckman separated the VSP into its component parts — the screw and the plate — and sought Section 510(k) approval for each. App., *infra*, 5a. These applications specified that the devices were intended to be used in the arm and leg long bones, rather than in the spine. The FDA determined that the screw and plate individually were substantially similar to pre-1976 devices and granted the applications in February 1986. *Id.* at 5a.

Despite the limited nature of the FDA clearance, "[i]n practice, surgeons often use[d] orthopedic screws which FDA ha[d] cleared for other purposes * * * as pedicle screws." FOOD & DRUG ADMIN., UPDATE ON PEDICLE SCREWS (1993) (quoted in Beck & Azari, 53 FOOD & DRUG L.J., at 77). Indeed, the FDA observed in 1995 that, since at least 1992, pedicle fixation with screws has been "considered to be the standard of care by the surgical community." 60 Fed. Reg. 51946, 51947 (1995). These uses, though widespread, were all off-label, because the FDA did not approve the marketing of bone screws for use in spinal surgery until January 1995. *Id.* at 51947-48.

C. The Orthopedic Bone Screw Product Liability Litigation

As just noted, after AcroMed placed its bone screws on the market, orthopedic surgeons used them, as well as bone screws produced by other manufacturers, as spinal fixation devices. After a national television program ran a story on alleged harm caused by this use of the bone screws, thousands of plaintiffs filed state-law suits against doctors, hospitals, universities, bone screw manufacturers, and regulatory consultants such as Buckman, alleging product defects and fraud in the manufacturers' representations to the FDA. The federal suits — approximately 2,300 civil cases involving 5,041 plaintiffs and 334 defendants — were consolidated in this multidistrict litigation. App., *infra*, 55a.

Plaintiffs did not contend that, in applying for Section 510(k) clearances, Buckman or AcroMed had misrepresented any objective fact, such as the size, shape, or technical characteristics of the screws or their equivalence to pre-1976 devices. Rather, plaintiffs claimed that Buckman and AcroMed deceived the FDA as to the "intended uses" of the devices, representing that they would be labeled for long bones while planning to market them for use in the spine. App., *infra*, 6a. In plaintiffs' view, the Section 510(k) clearances were the product of fraud under state law and, but for such fraud, the devices would never have been on the market and would not have been used in their pedicle surgery.

On March 2, 1995, the district court, relying on *Michael* v. *Shiley, Inc.*, 46 F.3d 1316 (3d Cir.), cert. denied, 516 U.S. 815 (1995), granted judgment on the pleadings on all "fraud on the agency" claims, holding that they were pre-empted both expressly by the MDA and impliedly by the federal scheme, which vests in the FDA exclusive authority to prosecute violations of the MDA. App., *infra*, 46a-53a. The MDA's express preemption provision, the district court explained, simply "does not permit courts to 'perform the same functions initially entrusted to the FDA.'" *Id.* at 49a (quoting *Michael*, 46 F.3d at 1329). Moreover, "[b]ecause the FDA possesses the proper authority to regulate this field, courts are prohibited from conducting 'a searching state inquiry into the inner workings of FDA procedures.'" *Ibid.* (quoting *Michael*, 46 F.3d at 1329); see also *id.* at 50a (reasoning that, "given the FDA's central role in reviewing and approving devices * * * [the agency] is in the best position to decide whether [a manufacturer] withheld material from the agency and, if so, the appropriate sanction"). Finally, the court reasoned that permitting "fraud on the agency" claims would be inconsistent with Congress's failure to authorize a private right of action under the Food, Drug and Cosmetic Act. *Ibid.*

Following this Court's *Medtronic* decision in 1996, plaintiffs sought to revive their "fraud on the FDA" claims and various defendants (including Buckman) moved the district court to reaffirm its prior decision. App., *infra*, 7a, 33a. On March 28, 1997, the district court reaffirmed its ruling. *Id.* at 33a-44a. The court agreed with plaintiffs' argument that *Medtronic* had undercut portions of its previous analysis, but concluded that "fraud on the agency" claims were still precluded because they were inconsistent with Congress's decision not to include a private right of action under federal law. *Id.* at 36a. Such claims, the district court reasoned, are simply "not interchangeable" with the claims at issue in *Medtronic*, which involved no allegation of fraudulent procurement of agency approval and therefore did not amount to a collateral attack on any agency decision. *Id.* at 40a.

Because "fraud on the FDA" was the sole claim against Buckman, the district court granted Buckman's motion for dismissal for failure to state a claim on which relief could be granted (App., *infra*, 45a) and certified the dismissal as a final order under Rule 54(b) of the Federal Rules of Civil Procedure. *Id.* at 54a-56a.

D. The Court of Appeals' Decision

A divided panel of the court of appeals reversed, over a "vehement[]" (App., *infra*, 32a) dissent by Judge Cowen. The majority concluded that *Medtronic*'s construction of the MDA's express preemption clause undermined the holding in *Michael* that state law "fraud on the FDA" claims are expressly and impliedly preempted. *Id.* at 13a-17a. The Third Circuit acknowledged that this holding was in direct conflict with the Seventh Circuit's decision in *Mitchell* v. *Collagen Corp.*, 126 F.3d 902 (1997), cert. denied, 118 S. Ct. 1300 (1998), which held that "fraud on the FDA" claims remain preempted after *Medtronic*. App., *infra*, 17a n.5.

The court of appeals rejected Buckman's express and implied preemption arguments. In the majority's view, the

MDA does not expressly preempt "fraud on the FDA" claims because the Section 510(k) process does not establish *any* "federal 'requirement'" that is "'applicable to the device' at issue here." App., *infra*, 13a. In equally sweeping fashion, the majority — adopting the position of a distinct minority of circuit courts — broadly declared that plaintiffs' common law claims do not impose *any* "state 'requirements' 'with respect to' that device." *Ibid.*

The Third Circuit also rejected the argument that "fraud on the agency" claims are impliedly preempted. App., *infra*, 16a. The majority recognized that "Congress has not created an express or implied private cause of action for violations of the FDCA or the MDA." *Id.* at 13a. But it "s[aw] no inconsistency" between Congress's decision to give the FDA the "exclusive prerogative" and discretion to enforce the requirements of federal law and allowing individuals to "bring common law fraudulent misrepresentation claims" to "enforce the FDCA." *Id.* at 18a.

Judge Cowen dissented. Unlike the majority, he was greatly troubled by permitting judges and juries hearing "fraud on the FDA" claims "to displace the FDA's judgment about whether a manufacturer has engaged in improper marketing." App., *infra*, 32a. Judge Cowen observed that "[t]he majority endorses a claim of 'fraud on the FDA' under circumstances that will expose manufacturers to fraud liability for seeking desirable innovations in a product's use, distort the penalty scheme established by the FDCA and its regulations, and generate substantial liability when manufacturers respond to doctors' widely accepted practice of purchasing medical products for off-label uses." *Id.* at 25a.

REASONS FOR GRANTING THE PETITION

The decision below creates one circuit conflict and extends another as to vitally important and frequently recurring issues of federal law: (1) whether "fraud on the agency" claims brought under state law are expressly or impliedly

preempted by a comprehensive federal regulatory regime administered by an expert administrative agency; and (2) whether this Court's decision in *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996), exempts from both express and implied preemption *all* state requirements that happen to be imposed through state tort laws of general applicability.

The Third Circuit is the first federal court of appeals to allow plaintiffs to bring tort actions under state law challenging FDA decisions as fraudulently obtained. Prior to *Medtronic,* every circuit to address the issue had held that such claims were preempted by federal law. As the court below acknowledged, its decision also squarely conflicts with a post-*Medtronic* decision of the Seventh Circuit. App., *infra*, 17a n.5. This intercircuit conflict impairs the stability and uniformity of the FDA's decisionmaking process.

Moreover, the circuit split over preemption of "fraud on the agency" claims extends beyond the MDA to cases involving similar regulatory schemes. See *Lewis* v. *Brunswick Corp.*, 107 F.3d 1494, 1502 (11th Cir. 1997) (Boat Safety Act preempts "fraud on the agency" claim), cert. dismissed, 118 S. Ct. 1793 (1998); *Kuiper* v. *American Cyanamid Co.*, 131 F.3d 656, 666 (7th Cir. 1997) (Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) "does not allow states to second-guess EPA's labeling decisions under the guise of enforcing the requirements of FIFRA itself"), cert. denied, 118 S. Ct. 1839 (1998). Thus, if permitted to stand, the decision below will allow litigants in the Third Circuit to circumvent express preemption provisions in a number of federal statutes.

Review of this case would also allow the Court to resolve widespread uncertainty over the meaning of *Medtronic*. In the wake of *Medtronic*, lower courts have disagreed over whether the MDA preempts only state "requirements" that apply exclusively to medical devices or whether it also preempts some state requirements imposed through laws of

general applicability. See *Goodlin* v. *Medtronic, Inc.*, 167 F.3d 1367, 1371 n.7 (11th Cir. 1999) (acknowledging conflict). The court below, like the Tenth Circuit, interpreted *Medtronic* as exempting state tort requirements from preemption simply because of their generality, while the Fourth, Sixth, Seventh and Ninth Circuits have rejected that view. Compare *Oja* v. *Howmedica, Inc.*, 111 F.3d 782, 789 (10th Cir. 1997), with *Mitchell* v. *Collagen*, 126 F.3d 902, 912 (7th Cir. 1997) (*Mitchell II*), cert. denied, 118 S. Ct. 1300 (1998); *Papike* v. *Tambrands, Inc.*, 107 F.3d 737, 741 (9th Cir.), cert. denied, 118 S. Ct. 166 (1997); *Martin* v. *Telectronics Pacing Sys., Inc.*, 105 F.3d 1090, 1097-98 (6th Cir. 1997), cert. denied, 118 S. Ct. 850 (1998); and *Duvall* v. *Bristol-Myers-Squibb Co.*, 103 F.3d 324, 330 (4th Cir. 1996). Because these disputes are attributable to ambiguities in the *Medtronic* decision itself, only this Court can bring clarity to this important area of federal law.

I. The Circuits Are Divided Over Whether "Fraud on the Agency" Claims Are Preempted By Federal Law

A. This Case Squarely Presents the Conflict

The decision below creates a conflict in the circuits over whether "fraud on the agency" claims are preempted under the MDA and other federal statutes containing analogous express preemption clauses. In contrast to the Third Circuit, the Seventh and Eleventh Circuits have held that collateral attacks on agency rulings through private tort actions are expressly and impliedly preempted. See *Mitchell II*, 126 F.3d at 913-14 (MDA preempts "fraud on the FDA" claims); *Lewis*, 107 F.3d at 1502; see also *Kuiper*, 131 F.3d at 666. This split is the result of disagreements over the meaning of *Medtronic*, as a brief review of its development demonstrates.

1. Prior to *Medtronic,* the lower courts were in general agreement that state law claims alleging fraud on the FDA either were expressly preempted by 21 U.S.C. § 360k(a) or were impliedly preempted both because they would interfere

with the FDA's exclusive authority over the regulatory regime for medical devices and because the MDA contains no private cause of action.[5]

Courts reasoned that "fraud on the FDA" claims were expressly preempted because they would impose requirements under state law that were "different from, or in addition to" (21 U.S.C. § 360k(a)) the FDA's clearance requirements under the MDA. See, *e.g.*, *Reeves*, 44 F.3d at 307 ("Allowing a jury or court to second-guess the FDA's enforcement of its own regulations contravenes Congress' expressly stated intent in § 360k(a) to eliminate attempts by states to impose conflicting requirements on medical device manufacturers."); *Michael*, 46 F.3d at 1329 ("Under § 360k, states may not * * * reach a different conclusion than the FDA."); *Mitchell I*, 67 F.3d at 1283 ("[I]f the court erred, and incorrectly posited the effect on the FDA's use and labeling decision, this would impose a [different or additional] state requirement."). State liability predicated on a manufacturer's failure to make certain disclosures to the FDA also raised the specter that a "manufacturer could potentially be subject to numerous inconsistent interpretations and applications of the MDA across different states, thus undermining the MDA's goal of uniformity." *Talbott*, 63 F.3d at 29.

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[5] See *Talbott* v. *C.R. Bard, Inc.*, 63 F.3d 25 (1st Cir. 1995), cert. dismissed, 517 U.S. 1230 (1996); *Mitchell* v. *Collagen Corp.*, 67 F.3d 1268, 1283 (7th Cir. 1995) (*Mitchell I*), vacated, 518 U.S. 1030 (1996); *Michael*, 46 F.3d at 1328-29; *Reeves* v. *AcroMed Corp.*, 44 F.3d 300, 306 (5th Cir.), cert. denied, 515 U.S. 1104 (1995); *Mears* v. *Marshall*, 905 P.2d 1154 (Or. Ct. App. 1995), vacated, 921 P.2d 966 (Or. 1996); see also *Scott* v. *CIBA Vision Corp.*, 38 Cal. App. 4th 307 (1995) (preemption of claim of negligence per se for failure to follow FDA regulations). But see *Evraets* v. *Intermedics Intraocular, Inc.*, 29 Cal. App. 4th 779 (1994) (no preemption).

Courts had also rejected "fraud on the agency" claims in other regulatory contexts. See *Papas* v. *Upjohn Co.*, 985 F.2d 516, 518-19 (11th Cir.) (FIFRA), cert. denied, 510 U.S. 913 (1993); *Oeffler* v. *Miles, Inc.*, 642 N.Y.S.2d 761, 765 (N.Y. Sup. Ct. 1996) (same); see also *Welchert* v. *American Cyanamid, Inc.*, 59 F.3d 69, 73 (8th Cir. 1995) (FIFRA preempts claims that would "allow state courts to sit, in effect, as super-EPA review boards that could question the adequacy of the EPA's determination of whether a pesticide registrant successfully complied with the specific labeling requirements of its own regulations"); *Worm* v. *American Cyanimid Co.*, 5 F.3d 744, 748 (4th Cir. 1993) (FIFRA preempts state law claim that manufacturer should have "voluntarily [made] additional disclosures and representations" and sought permission from the EPA to modify its label); *Wegoland Ltd.* v. *Nynex Corp.*, 27 F.3d 17, 21 (2d Cir. 1994) (filed-rate preemption doctrine bars claims of fraud on a rate-setting agency); *Taffert* v. *The Southern Co.*, 967 F.2d 1483, 1488-95 (11th Cir. 1992) (en banc) (same); *H.J., Inc.* v. *Northwestern Bell Tel. Co.*, 954 F.2d 485, 491-92 (8th Cir. 1992) (same).

In addition to express preemption, courts found that state law "fraud on the FDA" claims were impliedly preempted because they would "'stand[] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *Freightliner Corp.* v. *Myrick*, 514 U.S. 280, 287 (1995). Such claims would frustrate Congress's desire to create a unitary device marketing clearance system, enforced by the FDA, and would conflict with Congress's determination not to include a private cause of action under the MDA. See *Michael*, 46 F.3d at 1329 ("[P]ermitting a fraud claim based on false representation to the FDA would conflict with our precedent that plaintiffs may not bring implied causes of action for violations of the Food, Drug and Cosmetic Act."); *Talbott*, 63 F.3d 29-30 ("Congress * * * has not provided for [private policing of the MDA], choosing instead to place sole enforcement authority in the hands of the FDA.").

2. There matters stood at the time of the Court's decision in *Medtronic* v. *Lohr*, 518 U.S. 470 (1996). In *Medtronic*,

a 4-1-4 decision, the Court addressed negligence and strict liability claims brought against the manufacturer of an allegedly defective pacemaker that had received the FDA's Section 510(k) marketing clearance. Although the Court held that those claims were not expressly preempted, its fractured decision failed to articulate a single interpretation of the MDA preemption provision.

Both the plurality and Justice Breyer, who concurred in part and concurred in the judgment, rejected the argument that Section 360k(a) preempts *all* state law product liability claims relating to a medical device. See 518 U.S. at 487-89 (plurality); *id.* at 503-05 (Breyer, J. concurring). They also agreed that, to preempt state law, the manufacturing, design, and warning requirements imposed on a device by federal law must be "specific." See *id.* at 500; see also *id.* at 506-07 (Breyer, J.). Because the Section 510(k) process did not impose specific design requirements, and because the FDA's regulations did not impose specific warning and manufacturing requirements, the Lohrs' tort claims were not preempted. *Id.* at 493, 501; *id.* at 508 (Breyer, J.). Finally, the Court held unanimously, in dicta, that state law claims seeking to impose identical requirements are not "different from, or in addition to" federal requirements and are thus not preempted. *Id.* at 495 (majority); *id.* at 513 (opinion of O'Connor, J.).

3. Although *Medtronic* did not involve a "fraud on the agency" claim, and the Court's analysis was not broad enough to cover such claims, the unclear opinions have been a source of confusion for lower courts.

After *Medtronic,* the Third Circuit overruled its decision in *Michael* and held that "fraud on the agency" claims are not preempted. App., *infra*, 16a-17a; see also *Mears* v. *Marshall*, 944 P.2d 984, 992 (Or. Ct. App. 1997) (allowing "fraud on the agency" claims on remand after *Medtronic*). The Seventh Circuit, in contrast, reaffirmed its decision in *Mitchell I* and held that *Medtronic* does not save "fraud on the agency"

claims from preemption. See *Mitchell II*, 126 F.3d at 913-14. The division is also reflected in other courts. See *Carey* v. *Shiley, Inc.*, 32 F. Supp. 2d 1093, 1108 (S.D. Iowa 1998) (finding preemption); *Connelly* v. *Iolab Corp.*, 927 S.W.2d 848, 855 (Mo. 1996) (finding no preemption); *Green* v. *Dolsky*, 685 A.2d 110, 117 n.7 (Pa. 1996) (same), cert. denied, 520 U.S. 1168 (1997); *Dutton* v. *AcroMed Corp.*, 691 N.E.2d 738 (Ohio Ct. App. 1997) (same).

Courts finding no preemption have interpreted *Medtronic* as holding that the Section 510(k) process imposes no federal requirements, as opposed to merely no federal *design* requirements (App., *infra*, 13a), and that state law requirements that a manufacturer not defraud the FDA are identical to MDA requirements. See *Mears*, 944 P.2d at 992 n.4; *Connelly*, 927 S.W.2d at 855; *Green*, 685 A.2d at 414 n.7; *Dutton*, 691 N.E.2d at 742. See also *Goodlin*, 167 F.3d at 1375. Courts finding preemption, on the other hand, have held that the MDA approval process imposes federal disclosure requirements and that allegations of "liability under state law despite [the defendant's] conformity to the [FDA] requirements * * * must be considered preempted. Permitting such claims would add requirements that are 'different from, or in addition to,' those established" by the MDA. *Mitchell II*, 126 F.3d at 913-14; see *Carey*, 32 F. Supp. 2d at 1108.

This post-*Medtronic* conflict, moreover, has not been confined to the MDA, but extends to similar regulatory contexts. Compare *Lewis*, 107 F.3d at 1505 ("fraud on the Coast Guard" claim preempted under Federal Boat Safety Act), and *Kuiper*, 131 F.3d at 666 ("FIFRA does not allow states to second-guess EPA's labeling decisions under the guise of enforcing the requirements of FIFRA itself"), with *Hoelck* v. *ICI Americas, Inc.*, 584 N.W.2d 52, 61 (Neb. Ct. App.) (FIFRA does not preempt claim "based upon * * * failure to disclose relevant information to the EPA"), review denied (Oct. 28, 1998).

In contrast to the Seventh and Eleventh Circuits, the court below misunderstood the limited effect of *Medtronic* on the previously uniform rejection of "fraud on the agency" claims. Without resolution of the conflict by this Court, lower courts will continue to disagree over whether state juries can sit as "super-[agency] review boards that could question the adequacy of the [agency's] determination of whether a * * * registrant successfully complied with * * * [the agency's] regulations." *Kuiper*, 131 F.3d at 666 (quoting *Welchert* v. *American Cyanamid Inc.*, 59 F.3d 69, 73 (8th Cir. 1995)).

B. The Issue Presented by the Conflict is Recurring and of Great Practical Importance

The conflict in the circuits over "fraud on the agency" claims is particularly significant because of its far-reaching legal and practical effects. To begin with, because the Third Circuit's decision arises out of a multidistrict litigation proceeding involving literally thousands of cases, to which the decision below has already been applied, the opinion obviously has a far more substantial impact than the typical appellate decision in an ordinary product liability case.

Furthermore, "fraud on the agency" claims are not confined to the medical device context but have the potential to undermine a broad range of federal regulatory schemes.[6] "Virtually any federal agency decision that stood in the way of a lawsuit could be challenged indirectly by a claim that the

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[6] Numerous federal regulatory statutes contain preemption provisions with operative language virtually identical to the MDA. See, *e.g.*, FIFRA, 7 U.S.C. § 136v(b); Flammable Fabrics Act, 15 U.S.C. § 1203(a); Federal Hazardous Substances Act, *id.* § 1261 note (b)(1)(A); National Traffic and Motor Vehicle Safety Act, *id.* § 1392(d); Poison Prevention Packaging Act, *id.* § 1476(a); Consumer Product Safety Act, *id.* § 2075(a); Electronic Product Radiation Control Act, 21 U.S.C. § 360ss; Federal Boat Safety Act, 46 U.S.C. § 4306.

industry involved had misrepresented the relevant data or had otherwise managed to skew the regulatory result." *Lewis*, 107 F.3d at 1505. Under the MDA and analogous federal statutes, "fraud on the agency" claims thus provide a ready means to circumvent almost any preemptive federal requirement.[7] "Congress could not have intended for the process it so carefully put in place" by passing such statutes "to be so easily and thoroughly undermined." *Ibid.*

Even as limited to the MDA, the decision below will have an enormous impact on the medical device industry and on the public health. Allegations of fraud, even if unsubstantiated, may trigger burdensome, intrusive, and expensive discovery into product development files, often covering multi-year periods and evolving scientific evaluations of complex formulas and patient reactions.[8] In the highly competitive medical device industry, companies could bring such claims against manufacturers of successful devices,

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[7] Indeed, such claims may be brought under state law even where, as here, the agency itself does not believe it was "defrauded." Despite the fact that plaintiffs filed comments with the FDA detailing the allegations of fraud that form the basis of their claims, the FDA granted permission for the bone screws at issue to be labeled for use in spinal fixation. See *In re Orthopedic Bone Screw Prods Liab. Litig.*, 1995 WL 764580, at *5-*6 (E.D. Pa. Dec. 14, 1995); 63 Fed. Reg. 40025 (1998).

[8] These discovery proceedings could embroil the agency in time-consuming and disruptive private litigation, as litigants seek to obtain the best evidence about whether the agency was defrauded and, if so, what the agency would have done in the absence of the fraud. This case provides a compelling example. Petitioner and other defendants submitted strong evidence that the "fraud" alleged by plaintiffs — the submission of separate Section 510(k) applications for the component plates and screws of the AcroMed system — was in fact *suggested by FDA personnel*. See Pet. C.A. Br. at 15-18; Pet. C.A. App. Tab 2, Exhs. 1-2.

asserting that FDA actions were obtained through fraud. The FDA, not the courts, is the appropriate forum for considering such claims, through the agency's established procedures. See, *e.g.*, 21 C.F.R. §§ 10.25, 10.30, 10.33, and 10.35.

What is more, because "fraud on the agency" claims would subject medical device manufacturers to a duty to comply with the shifting and uncertain requirements imposed by juries applying the common law of the 50 states, manufacturers could never be certain that their submissions to the FDA were adequate. They would be compelled to inundate the agency with unnecessary data and speculative impressions in order to foreclose future state law claims that they procured the FDA's clearance through fraudulent concealment. At the same time, manufacturers would be far more reluctant to respond in valid, nonpromotional ways (such as by sending reprints of scientific articles) to physician inquiries concerning off-label uses of their products, for fear that such communications would be taken as evidence of the manufacturer's "true" "intended use" for the device and "fraud on the agency."

Armed with less information, many physicians would make less informed treatment decisions and might also be discouraged from engaging in off-label uses. But, as noted above, the practice of using drugs and medical devices for purposes other than those designated by the manufacturers during the FDA approval process is both extremely common and largely beneficial to patients. See PHYSICIANS' DESK REFERENCE COMPANION GUIDE 1623-54 (1998) (listing common off-label uses for nearly 1000 medical conditions). Indeed, the FDA is well aware of the prevalence and public benefits of such off-label uses. See FDA DRUG BULL. 12:4-5 (1982) (quoted in 59 Fed. Reg. 59820, 59821 (1994)). Given the widespread use of devices for off-label purposes, it is inevitable that manufacturers' submissions to the FDA will vary from the drugs' or devices' eventual uses — a circumstance that renders manufacturers particularly susceptible to the claim that they "defrauded" the federal agency.

Finally, "fraud on the FDA" claims, such as this one, that allege fraud in an "intended use" statement (made before any marketing has taken place) could lead to liability absent proof of *any* actual marketing violations. As a practical matter, however, such claims would "throw[] into the jury box" the difficult, policy-laden question of if and "when unacceptable 'marketing' has taken place" (App., *infra*, 29a (Cowen, J., dissenting)). Congress and the FDA have developed complex statutes and regulations explaining when manufacturers may disseminate information on off-label uses. See 21 U.S.C. §§ 360aaa to 360aaa-6; 63 Fed. Reg. 64556 (1998). If "fraud on the agency" claims are allowed to proceed, "[t]he penalties attached to a violation of the FDA's regulations will often be substantially increased, and enforcement of violations will no longer be controlled by the FDA's prosecutorial discretion." App., *infra*, 28a (Cowen, J., dissenting). In sum, as Judge Cowen correctly noted, "when juries are permitted to displace the FDA's judgment about whether a manufacturer has engaged in improper marketing, they will fail to provide a consistent standard, inhibit valuable exchange of information on off-label uses, and needlessly raise the price of drugs and medical devices." *Id.* at 32a.

II. The Decision Below Reflects Widespread Uncertainty Over the Meaning of *Medtronic* v. *Lohr*, Which This Court Alone Can Dispel

Wholly apart from its impact on "fraud on the agency" claims, the decision in *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996), has engendered a sharp conflict in the circuits on a fundamental question of immense importance to the scope of MDA preemption: whether the MDA was intended to preempt state laws of general applicability. See *Goodlin*, 167 F.3d at 1371 n.7 (noting circuit split); *Mitchell II*, 126 F.3d at 913 n.4 (same). Just over a year ago, the Solicitor General acknowledged "the division among the lower courts" on "questions concerning Section 360k's preemption of state common or statutory law applied in tort suits" and recom-

mended that the Court "grant review and definitively resolve the conflict" in an appropriate case. No. 96-1405 U.S. Br. at 18, *Smiths Indus. Med. Sys.* v. *Kernats*.

The confusion in the lower courts is traceable to Justice Breyer's tie-breaking vote in *Medtronic* (see *Mitchell II*, 126 F.3d at 912; *Papike*, 107 F.3d at 742) and to the effect of an FDA regulation interpreting the MDA's express preemption provision, 21 U.S.C. § 360k(a) (preempting state requirements *"with respect to a device"* that are "different from, or in addition to" federal requirements) (emphasis added).[9] The FDA has construed the highlighted language to mean that state requirements are not preempted if they are "requirements of general applicability." See 21 C.F.R. § 808.1(d)(1)

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[9] The lower courts are in dispute over whether deference is owed to an administrative agency's interpretation of an express preemption clause. See *Commonwealth Edison Co.* v. *Vega*, 1999 WL 212210, at *5 (7th Cir. April 13, 1999) (noting circuit conflict); see also *Massachusetts* v. *United States Dep't of Transp.*, 93 F.3d 890, 894 (D.C. Cir. 1996) (stating that "[n]either the Supreme Court nor this one has ever definitively decided" this issue). Compare *Brannan* v. *United Student Aid Funds*, 94 F.3d 1260, 1263 (9th Cir. 1996) (deferring to agency interpretation), cert. denied, 521 U.S. 1106 (1997), *Gustafson* v. *City of Lake Angelus*, 76 F.3d 778, 786 (6th Cir. 1996) (same), *Time Warner Cable* v. *Doyle*, 66 F.3d 867, 876 (7th Cir. 1995) (same), and *Elizabeth Blackwell Health Ctr. for Women* v. *Knoll*, 61 F.3d 170, 182 (3d Cir. 1995) (same), with *Grunbeck* v. *Dime Svg. Bank*, 74 F.3d 331, 341 (1st Cir. 1996) (refusing to defer to agency interpretation of "bare statutory language" of preemption provision); *Teper* v. *Miller*, 82 F.3d 989, 998 (11th Cir. 1996) (opinion of Kravitch, J.) ("it is not at all clear" that a court should defer to agency views on preemption); *Brannan*, 94 F.3d at 1268 (Fletcher, J., dissenting) (no deference to agency preemption interpretations), *Knoll*, 61 F.3d at 185 (Nygaard, J., dissenting) (same), and *Colorado Public Utilities Comm'n* v. *Harmon*, 951 F.2d 1571, 1579 (10th Cir. 1991) (same).

(no preemption of "State or local requirements of general applicability where the purpose of the requirements relates either to other products in addition to devices * * * or to unfair trade practices in which the requirements are not limited to devices").

The Court's opinion in *Medtronic*, which Justice Breyer joined, agreed that under the FDA's interpretation of the MDA preemption provision, only state requirements that are "specific" are subject to preemption. See 518 U.S. at 500; see also *id.* at 506-07 (Breyer, J.). But the Court also stated: "[W]e do not believe that this statutory and regulatory language necessarily precludes 'general' federal requirements from ever pre-empting state requirements, or 'general' state requirements from ever being pre-empted * * * ." *Id.* at 500; see also *id.* at 514 (opinion of O'Connor, J.) (noting that "the statutory language does not indicate that a requirement must be specific, either to preempt or to be preempted"). The majority nevertheless held that the tort claims involved in that case "escape pre-emption, not because the source of the duty is a judge-made common-law rule, but rather because their generality leaves them outside the category of requirements that § 360k envisioned to be 'with respect to' specific devices." *Id.* at 501 (plurality); *id.* at 508 (Breyer, J.).

In his separate opinion, however, Justice Breyer agreed with the four dissenting Justices who had rejected reliance on the FDA preemption regulation. See 518 U.S. at 503 ("I basically agree with Justice O'Connor's discussion of [whether the MDA will ever preempt a state law tort action] and with her conclusion."); *id.* at 511 (opinion of O'Connor, J.) (concluding that state common law damages actions can be preempted). Justice Breyer also indicated that he disagreed with the plurality "that future incidents of MDA pre-emption of common-law claims will be 'few' or 'rare[.]'" *Id.* at 508. And Justice Breyer explained that the state requirements that can be preempted include "a standard of care or behavior imposed by a state-law tort action." *Id.* at 504-05. In fact,

Justice Breyer gave a lengthy explanation of how a state negligence claim, perhaps the paradigmatic general state common law requirement, can be a preempted state "requirement." *Id.* at 504.

Medtronic's inconsistency over whether generalized state tort claims can be preempted under the MDA has played itself out in the circuit courts. The court below and the Tenth Circuit have held that *Medtronic* bars preemption of state law claims of general applicability, citing the part of the plurality opinion that Justice Breyer joined but ignoring the reasoning of his separate concurrence.[10]

On the other hand, the Fourth, Sixth, Seventh and Ninth Circuits have held that the MDA can preempt general common law tort claims.[11] Focusing on the language of

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[10] See App., *infra*, 12a (general common law "state requirements * * * escape pre-emption * * * because their generality leaves them outside the category of requirements that § 360k envisioned to be 'with respect to' specific devices") (quoting *Medtronic*, 518 U.S. at 501); *id.* at 13a (the state tort claim of "fraud on the agency" presented no "state 'requirement' 'with respect to'" the bone screws at issue); *Oja*, 111 F.3d at 789 ("Like the * * * claim at issue in *Medtronic*, the general state common law requirements imposed by Oja's negligent * * * claim were not specifically developed 'with respect to' medical devices. * * * Instead, Oja's * * * claim is predicated upon a general duty applicable to every manufacturer * * *.") (citing *Medtronic*, 518 U.S. 501-02).

[11] See *Mitchell II*, 126 F.3d at 912 ("[I]n order to determine whether a common law cause of action is preempted * * * it is necessary * * * to determine whether the *final judgment* of the state court would impose on the manufacturer a burden incompatible with the requirements imposed by the FDA.") (emphasis added); *Papike*, 107 F.3d at 742 (finding preemption even though "generally applicable state law principles are involved"); *Martin*, 105 F.3d at 1099 (holding that a "generally applicable" negligent manufacturing claim was preempted); *Duvall*, 103 F.3d at 330

Justice Breyer's concurring opinion, these courts have concluded that

> it makes little sense to argue that Justice Breyer would write separately to make clear his position that duties arising under state common law can constitute state law 'requirements' which can be preempted by the MDA, and then agree that because tort law consists of generally applicable principles, it is always preempted * * *.

Mitchell II, 126 F.3d at 912 (quoting *Papike*, 107 F.3d at 742). The D.C., First and Eighth Circuits have adopted a similar interpretation of Justice Breyer's *Medtronic* concurrence in cases involving other regulatory statutes.[12]

This disarray is also reflected in the federal district and state courts.[13] Indeed, the conflict is all the more troubling

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(holding that "common-law causes of action" may be preempted by the MDA).

[12] See *Geier* v. *American Honda Motor Co.*, 166 F.3d 1236, 1240 & n.10 (D.C. Cir. 1999); *Symens* v. *SmithKline Beecham Corp.*, 152 F.3d 1030, 1055 (8th Cir. 1998); *Wilson* v. *Bradlees of New England, Inc.*, 96 F.3d 552, 554 (1st Cir. 1996), cert. denied, 519 U.S. 1149 (1997).

[13] Compare, *e.g.*, *Easterling* v. *Cardiac Pacemakers, Inc.*, 986 F. Supp. 366, 370 (E.D. La. 1997) (allowing preemption of state general common law claims); *Lake* v. *TPLC*, 1 F. Supp. 2d 84, 87 (D. Mass. 1998) (same); *Chmielewski* v. *Stryker Sales Corp.*, 966 F. Supp. 839, 842-43 (D. Minn. 1997) (same); *Richman* v. *W.L. Gore & Assoc.*, 988 F. Supp. 753, 757 (S.D.N.Y. 1997) (same); *Berish* v. *Richards Med. Co.*, 937 F. Supp. 181, 185 (N.D.N.Y. 1996) (same); *Steele* v. *Collagen Corp.*, 54 Cal. App.4th 1474, 1486-87 (1998) (same); *Hernandez* v. *Coopervision, Inc.*, 691 So.2d 639 (Fla. Dist. Ct. App. 1997) (same); *Weiland* v. *Telectronics Pacing Sys., Inc.*, 704 N.E.2d 854, 861 (Ill. App. Ct. 1998) (same), appeal allowed (Ill. Mar. 31, 1999) (Table, No.

because in eight states (California, Kentucky, Illinois, Michigan, Ohio, Oregon, Pennsylvania, and Washington), state appellate court decisions on MDA preemption of tort claims directly contradict those of the relevant federal court of appeals.[14] Resolution of such conflicts is essential to

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86903); *Connelly*, 927 S.W.2d at 854-55 (same); *Sowell* v. *Bausch & Lomb, Inc.*, 230 A.D.2d 77, 83-4 (N.Y. App. Div. 1997) (same); *Green*, 685 A.2d 110 (same); *Fry* v. *Allergan Med. Optics*, 695 A.2d 511 (R.I.) (same), cert. denied, 118 S. Ct. 374 (1997); *Worthy* v. *Collagen*, 967 S.W.2d 360, 371 (Tex. 1998) (same); with *Lakie* v. *SmithKline Beecham*, 965 F. Supp. 49, 53-54 (D.D.C. 1997) (general common law claims not preempted because of generality); *Armstrong* v. *Optical Radiation Corp.*, 50 Cal. App.4th 580 (1996) (same); *Kernats* v. *Smiths Indus. Med. Sys.*, 669 N.E.2d 1300 (Ill. App. Ct. 1996) (same), cert. denied, 118 S. Ct. 684 (1998); *Niehoff* v. *Surgidev Corp.*, 950 S.W.2d 816, 822-23 (Ky. 1997) (same), cert. denied, 118 S. Ct. 1187 (1998); *Walker* v. *Johnson & Johnson Vision Prods, Inc.*, 552 N.W.2d 679, 686 (Mich. Ct. App. 1996) (same); *Baird* v. *American Med. Optics*, 713 A.2d 1019, 1029-30 (N.J. 1998) (same); *Dutton*, 691 N.E.2d at 741-42 (same); *Mears*, 944 P.2d at 990 (same); *Wutzke* v. *Schwaegler*, 940 P.2d 1386, 1389-90 (Wash. Ct. App. 1997) (same), review denied, 953 P.2d 96 (Wash. 1998).

[14] Compare App., *infra*, 12a-13a (3d Cir.) (not allowing preemption), with *Green*, 685 A.2d 110 (Pa.) (allowing preemption); *Papike*, 107 F.3d at 741 (9th Cir.) (allowing preemption), with *Mears*, 944 P.2d at 990 (Ore.) (not allowing preemption), 50 Cal. App.4th 580 (Cal. Ct. App) (same), and *Wutzke*, 940 P.2d at 1389-1390 (Was. Ct. App.) (same); *Mitchell II*, 126 F.3d at 913 (7th Cir.) (allowing preemption) with *Kernats*, 669 N.W.2d 1300 (Ill. App. Ct.) (not allowing preemption); *Martin*, 105 F.3d at 1997-98 (6th Cir.) (allowing preemption), with *Walker*, 552 N.W.2d at 686 (Mich. Ct. App.) (not allowing preemption), *Niehoff*, 950 S.W.2d at 822-23 (Ky.) (same), and *Dutton*, 691 N.E.2d at 741-42 (Ohio Ct. App.) (same).

prevent forum shopping. See *Baldwin* v. *Alabama*, 472 U.S. 372, 374 (1985).

Because the scope of preemption varies widely among the circuits, medical device manufacturers, which do business in all 50 states, confront dramatic differences in liability exposure from state to state for the identical products. And because the conflict stems from ambiguities in this Court's decision in *Medtronic*, additional litigation in the lower courts is most unlikely to lead to further clarity. Without a definitive resolution, the MDA, designed to promote uniform regulation of life-saving medical devices, will instead continue to spawn inconsistent rulings.

III. The Decision Below Is Incorrect

A. The Court Below Erred In Concluding That "Fraud on the Agency" Claims Are Not Subject To Preemption Under *Medtronic*

There is no sound reason to suffer the harms discussed above because the Third Circuit's decision is incorrect. The court below arrived at the counterintuitive conclusion that the MDA does not preempt "fraud on the agency" claims by repeatedly misconstruing this Court's precedents.

1. *Medtronic* restated the general principles of an express preemption inquiry: courts should consider whether the case falls "in a field which the States have traditionally occupied," 518 U.S. at 485, as well as the "purpose of Congress" and the "structure and purpose of the statute as a whole." *Id.* at 485-86. The Third Circuit applied none of these factors, all of which counsel in favor of preemption of "fraud on the agency" claims. For example, unlike the product liability suit at issue in *Medtronic*, this case involves the accuracy of submissions *to a federal agency*, a field that the states have *never* occupied. Similarly, unlike the product liability suit in *Medtronic*, preempting plaintiffs' claims would not have the "effect of granting complete immunity from design defect

liability to an entire industry." *Id.* at 487. To the contrary, plaintiffs would still be able to bring personal injury suits against the manufacturers, as well as fraud claims for representations made to them or their physicians. Put another way, preemption here would not eliminate any claim that plaintiffs would have had under state law if the MDA had not been enacted.

Finally, the "structure and purpose of the statute as a whole" suggest preemption. The MDA and its accompanying regulations contemplate a unified federal approach to marketing clearance of medical devices, giving the FDA discretionary power both to require additional information from applicants (21 C.F.R. §§ 807.87(*l*), 807.92(d)) and to punish false statements in applications through rescinding approval, requiring corrective actions, or ordering a recall (see, *e.g.*, 21 U.S.C. §§ 331q(2), 336, 337(a); *Talbott*, 63 F.3d at 29; 56 Fed. Reg. 46191, 46200 (1991)).

2. Even when it understood *Medtronic*'s approach to MDA express preemption, the Third Circuit misapplied those principles. In particular, the court below erroneously applied the holding of five Justices in *Medtronic* that only "specific" federal requirements can preempt state laws that impose requirements "different from" or "in addition to" the federal requirements. See 518 U.S. at 500 (plurality); *id.* at 506-07 (Breyer, J.).

The Third Circuit transformed this Court's determination that the Section 510(k) process imposes *no federal design requirements* into a holding that the Section 510(k) process imposes *no federal "requirements" at all*. Compare 518 U.S. at 493-94 (rejecting preemption of design claim because the Section 510(k) process did not "'require' Medtronic's pacemaker to take any particular form for any particular reason") with App., *infra*, 12a ("The § 510(k) process * * * established no federal requirement 'applicable to a device' within the meaning of the MDA."). Given the detailed and

specific regulatory requirements of the Section 510(k) approval process (see 21 C.F.R. § 807.87), this leap of logic is simply indefensible.[15] In essence, the Third Circuit attempted to deny the existence of the very federal requirements that plaintiffs accused Buckman of violating.

The final misstep in the Third Circuit's express preemption analysis was its holding that "fraud on the agency" claims are not "different from, or in addition to" the Section 510(k) requirements. But to prevail on their fraud claim, plaintiffs would have to prove that Buckman was required to disclose its plans to violate wholly separate FDA marketing regulations in its Section 510(k) application. Federal law imposes no such disclosure requirements. Under the MDA, "intended use" is determined by "the objective intent of the persons legally responsible for the labeling of devices" (21 C.F.R. § 801.4); see also 21 U.S.C. § 360c(i)(1)(E)(i); 21 C.F.R. § 807.87(e)), not by the applicant's subjective expectations. As Judge Cowen observed, the majority "stretches the 'intended use' statement" into both a statement of subjective intent and "an all purpose guarantee that an applicant will not violate other FDA rules." App., *infra*, 27a. State law claims that would impose liability for failing to disclose information that the FDA itself does not require are certainly "different from" and "in addition to" the federal requirements and are preempted by Section 360k(a).

3. All else aside, it should be clear that *Medtronic* had no effect on implied preemption principles. This Court was explicit that even common law claims can still be "preempted under conflict pre-emption analysis." 518 U.S. at 503; see

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[15] For example, the Section 510(k) process requires that devices be "substantially equivalent" to pre-1976 devices in order to obtain marketing clearance. See 21 U.S.C. § 360e(b)(1)(B). Surely a state law that instead required a medical device to be "exactly identical" to a pre-1976 device would be preempted.

also *id.* at 507-08 (Breyer, J.). For this reason alone, the Third Circuit erred in holding that *Medtronic* undermined prior decisions holding that "fraud on the agency" claims were impliedly preempted.

As previously explained, plaintiffs' suit would require juries applying state law to determine what information should have been submitted to the FDA and whether the agency, if it had received that information, would have reached a different result on AcroMed's Section 510(k) application. Claims such as this would plainly frustrate the MDA's purpose of having uniform federal submission requirements and vesting all authority over medical device marketing in the FDA. See *Michael*, 46 F.3d at 1329; *Mitchell I*, 67 F.3d at 1283. As the Eleventh Circuit explained, "[r]egulatory fraud claims" are

> impliedly preempted for fundamental, systemic reasons. Permitting such claims would allow juries to second-guess federal agency regulators * * *. If that were permitted, federal regulatory decisions that Congress intended to be dispositive would merely be the first round of decision making, with later more important rounds to be played out in the various state courts.

Lewis, 107 F.3d at 1505.

Indeed, the conflict between "fraud on the agency" claims and the FDA's regulatory procedures is most stark in cases, such as this one, where the FDA has been presented with the very same evidence of "fraud" and determined that the device is properly on the market. See note 7, *supra*. Plaintiffs' claim, pure and simple, is that the FDA should not have granted Section 510(k) approval to the bone screws and should instead have required the more exacting premarket approval process. But the FDA, fully aware of plaintiffs' position, has only recently reiterated that "premarket approval is not necessary to provide reasonable assurance of the device's safety and effectiveness." 63 Fed. Reg. 40025,

40032 (1998). The FDA has gone so far as to reclassify the bone screws, deciding that pedicle fixation should be a labeled use for many of the devices and spinal conditions involved in this litigation. *Ibid.*

The essence of plaintiffs' state law claim is that the medical devices at issue "had no lawful access to the market for any purpose." App., *infra*, 23a. Yet, the FDA, applying federal law, has repeatedly concluded that the devices should be on the market. Plaintiffs' suit would "stand[] as an obstacle" to the accomplishment of that federal purpose. *Freightliner*, 514 U.S. at 287.

B. The Court Below Erred In Holding That State Tort Claims Are Not Preempted Because of Their Generality

The Third Circuit's conclusion that state tort law requirements are not preempted because of their generality contradicts the holding in *Medtronic*, the text of the preemption provision, and common sense.

As the Fourth, Sixth, Seventh and Ninth Circuits have recognized, common law tort claims can be preempted under the MDA. See pages 19-23, *supra*. This also was the view of five Justices in *Medtronic*, who stated that the MDA can preempt "a standard of care or behavior imposed by a state-law tort action." 518 U.S. at 504-05 (Breyer, J.); see also *id.* at 510-12 (opinion of O'Connor, J.).

Indeed, in *Medtronic*, the FDA's own lawyer — the Solicitor General — rejected the proposition on which the Third Circuit rested its holding: the phrase "with respect to" in Section 360k(a) means that common law claims are never preempted. The Solicitor General stated (Br. 17): "The Lohrs argue that the 'with respect to' phrase limits the scope of the provision to state requirements that *specifically refer or relate to medical devices*, and therefore excludes *general* common-law duties. *That argument is strained as a grammatical*

matter." (citation omitted and emphasis added). In fact, the Solicitor General maintained, exactly the opposite is true: "[T]he 'with respect to' clause *suggests that such a 'requirement' may be one of general applicability.*" *Id.* at 18 (emphasis added). The Solicitor General went on to argue that common law duties qualified as "requirements" within the meaning of Section 360k(a). *Id.* at 15-19, 25 n.20.

The Third Circuit's position lacks any support in the text of the MDA. The language of Section 360k(a) broadly preempts "any" state requirement that affects "a device intended for human use," is "different from, or in addition to" any federal requirement, and "relates to" either "the safety or effectiveness of the device" or "any other matter included in a requirement applicable to the device under [the MDA]." 21 U.S.C. § 360k(a). Only a strained interpretation of these deliberately broad phrases can sustain the Third Circuit's determination that Section 360k(a) bars preemption of generally applicable tort requirements even when they are applied in the specific context of medical devices.

Finally, a blanket exclusion of generally applicable state tort claims would be nonsensical. There is no reason to believe that Congress cared about the form, as opposed to the content, of state requirements applicable to medical devices or intended to allow the states to avoid preemption through creative legislative drafting. As this Court has recognized in other preemption settings, recognition of a broad exception for "generally applicable" state requirements would create "an utterly irrational loophole." *Morales* v. *Trans World Airlines, Inc.*, 504 U.S. 374, 386 (1992); accord *Pilot Life Ins. Co.* v. *Dedeaux*, 481 U.S. 41, 47-48 (1987); *San Diego Bldg. Trades Council* v. *Garmon*, 359 U.S. 236, 244 & n.3 (1959). The same is true here.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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MAY 1999

APPENDICES

APPENDIX A

In re ORTHOPEDIC BONE SCREW PRODUCTS LIABILITY LITIGATION,

Plaintiffs Legal Committee, Appellant.

No. 97-1783.

United States Court of Appeals, Third Circuit.

Argued June 9, 1998.

Decided Nov. 17, 1998.

Before: STAPLETON, COWEN and RENDELL, Circuit Judges.

OPINION OF THE COURT

STAPLETON, Circuit Judge:

This case involves thousands of individual plaintiffs-appellants who claim that they suffered injuries resulting from the implantation of orthopedic bone screws into the pedicles of their spines. Over 2,000 individual actions were consolidated for pre-trial proceedings pursuant to the multi-district litigation statute, 28 U.S.C. § 1407. This appeal involves plaintiffs' allegations that one defendant, Buckman Company, Inc. ("Buckman"), made misrepresentations to the Food and Drug Administration ("FDA") serious enough to play a substantial role in the events which resulted in their injuries. The district court granted Buckman's motion to dismiss this state-law "fraud on the FDA" claim, determining that: (1) the claim was "precluded by virtue of the fact that the MDA [i.e., the Medical Device Amendments of 1976, 21 U.S.C. §§ 360c-360k, to the Federal Food, Drug, and Cosmetic Act of 1938 ("FDCA"), 21 U.S.C. § 301 et seq.] does not provide for a private right of action," App. at 157;

and (2) plaintiffs could not, as a matter of law, demonstrate proximate causation between the misrepresentations to the FDA and any injuries suffered. App. at 158-59. We will reverse.

I.

A.

The orthopedic bone screw devices that are the subject of this suit are regulated by the FDA pursuant to the MDA. Congress enacted the MDA to address concerns regarding the safety and effectiveness of the wide variety of medical devices introduced into the market. See *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 476, 116 S. Ct. 2240, 135 L.Ed.2d 700 (1996). The MDA requires classification of medical devices into three categories based upon the risk that they pose to the public. Class I devices present no unreasonable risk of illness or injury and are subject only to general manufacturing controls. See 21 U.S.C. § 360c(a)(1)(A). Class II devices are potentially more harmful and are subject to federal performance regulations. See *id.* § 360c(a)(1)(B). Finally, Class III devices "present[ ] a potential unreasonable risk of illness or injury" and are subject to the strictest regulation. *Id.* § 360c(a)(1)(C).

Class III devices may not be introduced into the market until the manufacturer provides the FDA with "reasonable assurance" that the device is both safe and effective. See *id.* § 360e(d)(2). This "premarket approval" process requires a manufacturer to submit, and the FDA to review, "all information, published or known ... or which should reasonably be known ... concerning investigations which have been made to show whether or not such device is safe and effective." *Id.* § 360e(c)(1)(A). In addition, the manufacturer must provide the FDA with a full statement of design and manufacturing plans, as well as any additional information requested by the agency. See *id.* § 360e(c)(1). Securing premarket approval is an arduous and time-

consuming process; each submission requires an average of 1,200 hours of FDA review. See *Lohr*, 518 U.S. at 477, 116 S. Ct. 2240.

There are three important exceptions to the requirement that Class III medical devices receive premarket approval before being placed on the market. First, a manufacturer can obtain an Investigational Device Exemption ("IDE"), which allows limited use of an experimental medical device to gather the type of data necessary to support a premarket approval application. See 21 U.S.C. § 360j(g). Though an IDE allows use of a Class III device in clinical trials, it does not permit introduction to the general public.

Second, the MDA allows Class III devices that were in commerce prior to its enactment to remain on the market until the FDA initiates and completes a premarket approval analysis for those "predicate" devices. See *id.* § 360e(b)(1)(A). This "grandfathering" provision reflects Congress' recognition "that existing medical devices could not be withdrawn from the market while the FDA completed its PMA analysis for those devices." *Lohr*, 518 U.S. at 477-78, 116 S. Ct. 2240.

Third, to prevent manufacturers of grandfathered devices from monopolizing the market while new devices wait for FDA approval, and to ensure that improvements to existing devices are introduced quickly, the MDA allows devices that are "substantially equivalent" to an existing predicate device to avoid the premarket approval process. See *Lohr*, 518 U.S. at 478, 116 S. Ct. 2240; 21 U.S.C. § 360e(b)(1)(B). The procedure a manufacturer follows to take advantage of this exception is known colloquially as the "§ 510(k) process," after the number of the relevant section in the original Act. A § 510(k) application must contain information supporting the device's substantial equivalence to a predicate device, proposed labeling for the device, and any additional information requested by the FDA. See 21 C.F.R. § 807.87.

For a device to be approved under the § 510(k) process, the FDA must determine that the new device has the same intended use as the predicate device and that it possesses the same technological characteristics or is as safe and effective as the predicate device. See 21 U.S.C. § 360c(i)(1)(A).[1] The advantage of the § 510(k) process is significant to manufacturers: review of a § 510(k) application by the FDA requires an average of only twenty hours of agency time, compared to the 1,200 hours required for full premarket approval. See *Lohr*, 518 U.S. at 478-79, 116 S. Ct. 2240.

B.

Buckman is a regulatory consultant to medical device manufacturers, and was retained by the AcroMed Corporation to act as its liaison to the FDA in its attempt to secure marketing clearance for its product. AcroMed initiated the § 510(k) process to secure marketing clearance for its orthopedic bone screw device, known as the Variable Screw Placement ("VSP") Spinal Plate Fixation System, in September 1984.[2] In this application, AcroMed indicated that

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[1] A device is "substantially equivalent" to a predicate device if it:

> (i) has the same technological characteristics as the predicate device, or
>
> (ii) (I) has different technological characteristics and the information submitted that the device is substantially equivalent to the predicate device contains information, including appropriate clinical or scientific data if deemed necessary by the Secretary ..., that demonstrates that the device is as safe and effective as a legally marketed device, and (II) does not raise different questions of safety and effectiveness than the predicate device.

21 U.S.C. § 360c(i)(1)(A).

[2] A second device, known as the ISOLA Spine Fixation System, is also at issue in this appeal. Since the facts alleged regarding both

it intended to market the device for use in spinal surgery. The FDA rejected the request, determining that the VSP device was a Class III device and was not substantially equivalent to any predicate device.

In September 1985, AcroMed, through Buckman, filed a second application for marketing clearance through the § 510(k) process. The application provided additional information about the VSP device and again indicated its intended use in spinal surgery. The FDA again rejected the application, determining that the device was not substantially equivalent to a predicate device and that it posed potential risks not exhibited by other spinal-fixation systems.

In December 1985, AcroMed and Buckman filed two final § 510(k) applications seeking market approval for its product. AcroMed and Buckman split the VSP device into its component parts, renamed them "nested bone plates" and "cancellous bone screws" and filed a separate § 510(k) application for each component. In both applications, a new intended use was specified: rather than seeking clearance for spinal applications, they sought clearance to market the plates and screws for use in the long bones of the arms and legs. AcroMed and Buckman claimed that the two components were substantially equivalent to predicate devices used in long bone surgery. The FDA approved the devices for this purpose in February 1986.

The subject of this appeal is plaintiffs' fraud on the FDA claim against Buckman. Plaintiffs allege that AcroMed, through Buckman, made material misrepresentations in its successful § 510(k) submission to the FDA. Specifically, plaintiffs allege that AcroMed, through Buckman, "sought approval of its VSP plates and screws for use in long bones simply as a pretext in order to market the device for its true

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systems are substantively similar, our discussion of the VSP system applies with equal force to the ISOLA system.

intended use in the spine." App. at 58. According to the plaintiffs, Buckman, AcroMed and other defendants contrived a strategy in which they would (1) misrepresent the intended use of the screw system to the FDA, (2) obtain the FDA's approval to market the system for that misrepresented use, and (3) subsequently market the system for a use, spinal surgery, for which they could not obtain the FDA's approval. Plaintiffs contend that, as a result of the mis-representations to the FDA, a § 510(k) clearance was issued, allowing the devices access to the market they would not otherwise have had.

C.

In 1994, the Judicial Panel on Multidistrict Litigation designated the district court as the transferee court for *In re: Orthopedic Bone Screw Liability Litigation*, MDL No. 1014. Since that time, some 2,300 civil actions have been transferred to the district court. In March 1995 the district court granted a motion brought by AcroMed and other defendants to dismiss plaintiffs' fraud on the FDA claims, determining that those claims (1) were preempted by the MDA, and (2) impermissibly implied a private right of action for violation of the FDCA. See App. at 28 (Pretrial Order No. 12). Relying on our decision in *Michael v. Shiley, Inc.*, 46 F.3d 1316 (3d Cir.1995), the district court's order purported to "dismiss[ ] all fraud on the FDA ... claims contained in any pleading" in the consolidated litigation. App. at 37.

Subsequently, in June 1996, the Supreme Court decided *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 116 S. Ct. 2240, 135 L.Ed.2d 700 (1996), in which the Court addressed the scope of MDA preemption for the first time. As a result of that decision, plaintiffs filed amended complaints which re-asserted fraud on the FDA claims against Buckman and other defendants. AcroMed and other defendants filed a motion to reaffirm Pretrial Order No. 12 in light of *Lohr*. Buckman

joined this motion, but also simultaneously filed its own motion to dismiss the fraud on the FDA claims against it. The district court granted AcroMed's motion and reaffirmed Pretrial Order No. 12, though on modified grounds. The district court recognized that *Lohr* likely invalidated one of the two grounds for its prior decision. Nevertheless, it concluded that *Lohr* did not completely undermine Pretrial Order No. 12 because *Lohr* "did not address claims of fraud on the FDA with respect to the absence of a private right of action for violations of the FDCA." App. at 157. The district court determined that allowing a fraud on the FDA claim would essentially create a private right of action for violation of the FDCA and that, "in view of the FDA's exclusive prosecutorial discretion ... any grant of an implied private right of action would be contrary to the letter and spirit of the statute." App. at 153.

In addition, the district court determined that dismissal of plaintiffs' fraud on the FDA claims was warranted because "the alleged fraud cannot be said to have been a proximate cause of plaintiffs' alleged injuries." App. at 158. The court reasoned that since any misrepresentations were directed only to the FDA and any injuries were caused only by unrelated physicians, the connection between the alleged fraud and plaintiffs' injuries "is so tenuous, if existent at all, that the former cannot be said to be a 'substantial factor' in causing the latter." App. at 159 (citations omitted).

After granting AcroMed's motion to dismiss the fraud on the FDA claims, the district court subsequently granted Buckman's identical motion to dismiss "for the reasons stated in Pretrial Order No. 845." App. at 162 (Pretrial Order No. 900). Thereafter, the district court certified Pretrial Order

No. 900 as a final order pursuant to Fed.R.Civ.P. 54(b). See App. at 163 (Pretrial Order No. 1067).[3]

We have jurisdiction over the final order of the district court pursuant to 28 U.S.C. § 1291. We exercise plenary review over a dismissal for failure to state a claim, and we accept all factual allegations of the plaintiffs as true and draw all reasonable inferences therefrom in their favor. See *Trump Hotels & Casino Resorts, Inc. v. Mirage Resorts Inc.*, 140 F.3d 478, 483 (3d Cir. 1998).

II.

Count I of the complaint tendered to us as representative is entitled "Fraud (on the FDA)." App. at 55. It alleges that: (1) "[i]n response to the FDA's inquiry concerning the intended use of the bone plates and bone screws, ... Buckman, acting as representative of AcroMed ... intentionally and falsely represented to the FDA that ... [they were] 'intended for use in appropriate fractures of long bones of both the upper and lower extremity and such other flat bones,'" App. at 58; (2) "Buckman ... intended for the FDA to clear the VSP device components based upon this misrepresentation," *id.*; (3) "[i]n reliance on this express misrepresentation, the FDA determined ... that AcroMed's nested bone plates and cancellous bone screws were substantially equivalent to devices marketed ... prior to May 28, 1976 for the intended use represented by AcroMed" and issued a § 510(k) clearance, id.; (4) "the VSP device was intended exclusively for use in the spine," *id.*; (5) "the only

[3] Certification was proper for Pretrial Order No. 900 because plaintiffs asserted no other claims against Buckman other than the fraud on the FDA claims. As a result, Buckman is the only proper party to this appeal. Although Sofamor, S.N.C. and Danek Medical, Inc. submitted a joint brief and an appendix as appellees, we treated those documents as submissions of amici curiae and issued an appropriate order to that effect.

purpose for which AcroMed's plates and screws were sold was for use in the spine," *id.*; (6) "[t]he FDA was ignorant of the fact that these devices and device components were intended by AcroMed to be used as pedicle screw fixation devices," *id.* at 63; (7) "[w]ere it not for these fraudulent acts and statements, the FDA would not have issued § 510(k) clearances for AcroMed's pedicle screw fixation devices for any purpose, the devices would not have been introduced into interstate commerce, and Plaintiff would not have been exposed to the dangerous device which was surgically implanted in the Plaintiff's spine," *id.*; and (8) "[a]s a direct and proximate result of the wrongful conduct alleged in Count I of this Complaint, Plaintiff has suffered, and will continue to suffer, severe physical harm, including injury to Plaintiff's spine," *id.* at 63-64.

Count I is thus drafted to track the elements of a common law cause of action for fraudulent misrepresentation: (1) a representation of fact, opinion, intention or law; (2) knowledge of its falsity; (3) an intent to induce reliance; (4) justifiable reliance; and (5) resulting injury. See *Restatement (Second) of Torts* § 525 *et seq.*

At the time of the decision here appealed, the bone screw cases were still at the pleading stage. While it is clear that the plaintiffs' "fraud on the FDA" claims are based on state rather than federal law, neither the parties nor the district court have yet addressed the potential choice of law issues and those issues are not before us. We note at the outset, however, that the controlling state law of fraudulent representation in some cases may be different from that in other cases. This is important to our analysis because the district court's dismissal of all "fraud on the FDA" claims was appropriate only if federal law forecloses resort to state law or if the allegations comprising those claims do not state a claim on which relief can be granted under any of the potentially applicable state laws. We first address the issue of whether federal law forecloses resort to state law and then

turn to the issue of whether the allegations of the complaints may state a claim under any of the potentially applicable state laws.

III.

A.

The MDA contains the following preemption provision:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k.[4]

The FDA regulations interpreting § 360k of the MDA provide in part as follows:

> State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect devices that are not preempted

[4] Subsection (b) of § 360k grants authority to the Secretary of Health and Human Services to grant exemptions from preemption and is not pertinent here.

> ... because they are not "requirements applicable to a device" within the meaning of section [360k] of the act. The following are examples ...:
>
> (1) Section [360k] does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices.
>
> (2) Section [360k] does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act.

21 C.F.R. § 808.1(d).

In *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 116 S. Ct. 2240, 135 L.Ed.2d 700 (1996), the Supreme Court applied these statutory and regulatory provisions in the context of a suit against the manufacturer of a pacemaker that had been cleared as a Class III device under § 510(k). Lohr, the plaintiff there, asserted common law negligence and strict liability claims based on the design of the pacemaker as well as state law claims based on defective manufacture and mislabeling. The Court held that these claims were not preempted.

The Court gave the preemption provision of the statute a narrow reading. It stressed that preemption occurs under § 360k only when (1) there is a state "requirement" "with respect to a device;" (2) there is a federal "requirement" "applicable to the device" under the MDA; (3) the state requirement is "different from, or in addition to" the federal requirement; and (4) the state requirement relates to the safety or effectiveness of the device or some matter included in the federal requirement. See 518 U.S. at 500, 116 S. Ct. 2240.

The Court found that issuance of a § 510(k) clearance "did not 'require' Medtronic's pacemaker to take any particular form for any particular reason; the agency simply allowed the pacemaker, as a device substantially equivalent to one that existed before 1976, to be marketed without running the gauntlet of the MDA process." 518 U.S. at 483-84, 116 S. Ct. 2240. The § 510(k) process thus established no federal requirement "applicable to a device" within the meaning of the MDA. "Similarly, the general state common law requirements [relied upon by Lohr] were not specifically developed 'with respect to' medical devices. Accordingly, they [were] not the kinds of requirements that Congress and the FDA feared would impede the ability of federal regulators to implement and enforce specific federal requirements." *Id.* at 501, 116 S. Ct. 2240. The general obligations imposed by the state common law relied upon by Lohr were "no more a threat to federal requirements than would be a state-law duty to comply with local fire prevention regulations and zoning codes, or to use due care in the training and supervision of a workforce. These state requirements therefore escape pre-emption, not because the source of the duty is a judge-made common-law rule, but rather because their generality leaves them outside the category of requirements that § 360k envisioned to be 'with respect to' specific devices such as pacemakers." *Id.* at 501-02, 116 S. Ct. 2240.

The Court also held that "[n]othing in § 360k denies [a state] the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements.... The presence of a damages remedy does not amount to the additional or different 'requirement' that is necessary under the statute; rather, it merely provides another reason for manufacturers to comply with identical existing 'requirements' under federal law." *Id.* at 495, 116 S. Ct. 2240.

B.

Based on *Lohr*, it is apparent that, within the meaning of § 360k, there is no federal "requirement" "applicable to the device" at issue here; nor is there a state "requirement" "with respect to" that device. Moreover, the state common law relied upon does not impose any obligation on Buckman inconsistent with federal law. As plaintiffs stress, 18 U.S.C. § 1001 makes it a crime to make a fraudulent statement to a federal agency and 21 C.F.R. § 807.87(j) requires every pre-market notification to contain a statement that the information contained therein is believed to be truthful.

C.

Neither the district court nor Buckman takes issue with any of these conclusions concerning the effect of *Lohr* on the "fraud on the FDA" claims in this suit. The district court expressly acknowledged that *Lohr* was inconsistent with one of the two grounds it originally articulated for dismissing these claims. It nevertheless concluded that *Lohr* was consistent with dismissal because its alternative ground remained unaffected by *Lohr*. As the district court put it, "[w]hile Lohr may have affected the portion of [the court's prior decision] that relied on the doctrine of preemption, the portion of the court's reasoning based on the absence of an implied right of action [under the FDCA] remains in tact." App. at 152-53. We disagree.

It is, indeed, well established that Congress has not created an express or implied private cause of action for violations of the FDCA or the MDA. It is also true, as the district court pointed out, that this court, in *Michael v. Shiley, Inc.*, 46 F.3d 1316, 1329 (3d Cir. 1995), found this fact significant in the course of holding that a common law fraud claim against the manufacturer of a heart valve was preempted by the FDCA. We there concluded:

Under § 360k, states may not impose different requirements and thereby reach a different conclusion than the FDA. "[W]here the FDA was authorized to render the expert decision ..., it, and not some jury or judge, is best suited to determine the factual issues and what their effect could have been on its original conclusions." *King* [*v. Collagen Corp.*, 983 F.2d 1130,] 1140 [(1st Cir. 1993)] (Aldrich & Campbell, J.J. concurring). Under the MDA, states have no authority to police Shiley's compliance with the FDA's procedures. If Shiley knowingly misled the FDA in its PMA application, it is for the FDA to remedy that situation using the authority Congress gave it in the MDA.

Further, permitting a fraud claim based on false representations to the FDA would conflict with our precedent that plaintiffs not bring implied causes of action for violations of the *Food, Drug and Cosmetic Act*. *Gile v. Optical Radiation Corp.*, 22 F.3d 540, 544 (3d Cir.), cert. denied, 513 U.S. 965, 115 S. Ct. 429, 130 L.Ed.2d 342 (1994). Plaintiffs cannot circumvent this bar by characterizing their cause as a claim for state law fraud.

Michael, 46 F.3d at 1329. As we have noted, the district court recognized that the first reason we gave for our holding in *Michael* is untenable after *Lohr*. Nevertheless, it believed that it remained bound by our alternative rationale.

It is important to note at the outset that, contrary to the district court's suggestion, our alternative rationale in *Michael*, like our primary one, was necessarily based on the doctrine of preemption. Absent preemption by federal law (or a ground for stay or abstention, doctrines not pertinent here), a district court having jurisdiction of the parties and the subject matter cannot decline to enforce liability imposed by the relevant state common law. *See, e.g., Polselli v. Nationwide Mutual Fire Insurance Co.*, 126 F.3d 524, 527

n.1 (3d Cir. 1997) ("A federal court exercising diversity jurisdiction must apply the substantive law of the state whose laws govern the action."). *Cf. Erie R.R. Co. v. Tompkins*, 304 U.S. 64, 78, 58 S. Ct. 817, 82 L.Ed. 1188 (1938) ("Except in matters governed by the Federal Constitution or by Acts of Congress, the law to be applied in any case is the law of the State."). This is important to understand because " '[t]he purpose of Congress is the ultimate touchstone' in every pre-emption case." *Lohr*, 518 U.S. at 485, 116 S. Ct. 2240 (quoting *Retail Clerks v. Schermerhorn*, 375 U.S. 96, 103, 84 S. Ct. 219, 11 L.Ed.2d 179 (1963)). Unless Congress intends preemption, there is none. Accordingly, where Congress has expressed itself on preemption in a statute, "Congress' intent, of course, primarily is discerned from the language of the pre-emption statute and the 'statutory framework' surrounding it." *Id.* at 486, 116 S. Ct. 2240 (quoting *Gade v. National Solid Wastes Management Assn.*, 505 U.S. 88, 111, 112 S. Ct. 2374, 120 L.Ed.2d 73 (1992) (Kennedy, J., concurring)).

In *Michael*, we inferred from the fact that Congress created no private right of action for violations of the FDCA that it intended to foreclose suits based on state common law that would provide a remedy for conduct violative of that act. Ironically, a plurality of the Supreme Court in *Lohr* drew a diametrically opposed inference from the same fact. It viewed Congress' failure to provide a federal remedy as persuasive evidence of an intent not to preempt common law liability for the same conduct:

> Under Medtronic's view of the statute, Congress effectively precluded state courts from affording state consumers any protection from injuries resulting from a defective medical device. Moreover, because there is no explicit private cause of action against manufacturers contained in the MDA, and no suggestion that the Act created an implied private right of action, Congress would have barred most, if not all, relief for persons

> injured by defective medical devices. Medtronic's construction of § 360k would therefore have the perverse effect of granting complete immunity from design defect liability to an entire industry that, in the judgment of Congress, needed more stringent regulation in order "to provide for the safety and effectiveness of medical devices intended for human use," 90 Stat. 539 (preamble to Act). It is, to say the least, "difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct," *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251, 104 S. Ct. 615, 78 L.Ed.2d 443 (1984), and it would take language much plainer than the text of § 360k to convince us that Congress intended that result.

Lohr, 518 U.S. at 487, 116 S. Ct. 2240 (footnote omitted) (plurality).

More fundamentally, however, *Lohr* teaches that where Congress has expressed its intention with respect to preemption, we should look primarily to what it said. When it looked to what Congress said in § 360k, the Supreme Court in *Lohr* concluded that Congress did not intend to prevent a state from providing "a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements." *Lohr*, 518 U.S. at 495, 116 S. Ct. 2240.

Refusing to entertain Buckman's fraudulent misrepresentation claim solely because the statutory scheme does not contain a private cause of action would be the equivalent of finding preemption of state law claims contrary to the clear holding of *Lohr*. In short, *Lohr* overrules everything in *Michael* that would prevent a plaintiff from

pursuing a cause of action for fraudulent misrepresentation based on common law principles.[5]

D.

Buckman advances a number of preemption arguments in addition to the one adopted by the district court. In each instance, we conclude that *Lohr* counsels rejection.

Buckman argues that *Lohr* is distinguishable (1) because it "did not involve claims turning on FDA *procedures*, but rather claims that the product itself was defective," Buckman Br. at 12, and (2) because the target of the alleged fraud here is "a creature of statute" which has the sole responsibility for enforcing the FDCA and the regulation promulgated thereunder. Buckman Br. at 10.[6]

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[5] We respectfully disagree in this regard with the conclusion reached by the Court of Appeals for the Seventh Circuit in *Mitchell v. Collagen Corp.*, 126 F.3d 902 (7th Cir.1997). It there concluded that our holding in *Michael* survives *Lohr*. 126 F.3d at 914. While it did not explain its conclusion, one can infer from its earlier decision in the same case, 67 F.3d 1268, that it believes the first rationale for our decision in Michael retains vitality.

[6] Buckman and amici (in support of a similar argument) make specific reference to 21 U.S.C. § 337(a) and § 336. Section 337(a) provides:

> Except as provided in subsection (b) of this section, all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States.

Section 336 provides:

> Nothing in this chapter shall be construed as requiring the Secretary to report for prosecution ... minor violations of this chapter whenever he believes that the public interest will be adequately served by a suitable written notice or warning.

Once again, we look first to Congress' express message concerning preemption — § 360k. In the context of the text of that section as construed in *Lohr*, Buckman's suggested distinctions are simply unpersuasive. Indeed, given that there must be state and federal requirements *with respect to a device*, it is harder to argue preemption under § 360k based on FDA procedures than based on FDA substantive requirements for a regulated device.

We do not rule out the possibility that there may be some areas of preemption outside the scope of § 360k based on clear and direct conflicts between the requirements of state law and those of the FDCA. The existence of § 360k, its relatively narrow scope, and *Lohr*'s presumption against preemption of areas traditionally occupied by state law, however, counsel caution in finding implied preemption where no express preemption exists. Here, appellees' argument boils down to a contention that the litigation of suits of this kind is fundamentally inconsistent with the regulatory process established by the FDCA. We see no inconsistency between the FDA having the exclusive prerogative of bringing actions to enforce the FDCA and preserving the right of people in the plaintiffs' position to bring common law fraudulent misrepresentation claims. Moreover, we do not share appellees' apparent perception that litigation of such claims holds the potential for courts and juries second-guessing the FDA. Indeed, there is ample precedent, in related contexts, to support a claim premised on misrepresentations made to a federal agency. *See, e.g., Learjet Corp. v. Spenlinhauer*, 901 F.2d 198, 202-03 (1st Cir. 1990) (allowing aircraft purchaser's claim against manufacturer based on misrepresentation to Federal Aviation Administration); *Stanton by Brooks v. Astra Pharmaceutical Products*, 718 F.2d 553, 568-69 (3d Cir. 1983) (allowing patient's claims against drug manufacturer based on misleading the FDA); *Hawkins v. Upjohn Co.*, 890 F.Supp. 609, 612 (E.D. Tex. 1994) (same).

IV.

Buckman also asks us to affirm on the alternative ground that the complaints do not state a claim for fraudulent misrepresentation. Three reasons for such a conclusion are urged. First, it is said that the complaints do not, and cannot, allege causation. Second, it is argued that, in the context of a § 510(k) application, a statement of the intended purpose of the applicant, as a matter of law, is not a representation of fact, opinion, or intention. Finally, it is argued that the complaints do not, and cannot, allege reliance by the plaintiffs on the alleged misrepresentation by the FDA.

A.

The district court determined that plaintiffs' fraud on the FDA claims should be dismissed because "the alleged fraud cannot be said to have been a proximate cause of plaintiffs' alleged injuries." App. at 158. In the court's view, "[l]egal causation largely fails because the object of plaintiffs' fraud-on-the-FDA claim is the FDA and not the doctors who performed surgeries on the plaintiffs or the plaintiffs themselves. ... The causal connection between the alleged fraud committed on the FDA and plaintiffs' alleged injuries is so tenuous, if existent at all, that the former cannot be said to be a 'substantial factor' in causing the latter." App. at 158-59. While we are not in a position to canvass all the potentially applicable law, what we know about tort law generally makes us unwilling to say that all of the plaintiffs' claims will fail for want of the kind of a causation that will give rise to liability.

First, the mere fact that the alleged fraudulent misrepresentation was made to the FDA and not the plaintiffs does not necessarily preclude a finding of legally sufficient causation. Section 310 of the *Restatement (Second) of Torts* states, for example:

> An actor who makes a misrepresentation is subject to liability to another for physical harm which results from an act done by ... a third person in reliance upon the truth of the representation, if the actor
>
> (a) intends his statement to induce or should realize that it is likely to induce action by ... a third person, which involves an unreasonable risk of physical harm to the other, and
>
> (b) knows
>
> (i) that the statement is false, or
>
> (ii) that he has not the knowledge which he professes.

Another example is provided by our decision in *Stanton by Brooks v. Astra Pharmaceutical Products*, 718 F.2d 553 (3d Cir.1983). The plaintiff there, who had suffered brain damage as the result of an adverse reaction to the local anesthetic, Xylocaine, recovered a substantial judgment against the manufacturer of the drug. The plaintiff alleged that the defendant had misled the FDA by withholding information it was required to report concerning adverse effects previously suffered by others. We sustained the judgment against an attack that there was no legally sufficient causal connection between the defendant's misleading conduct and the plaintiff's injury. We concluded:

> The jury heard the testimony of four well qualified expert witnesses ... from which they could infer ... (1) that had the FDA had these reports, it would have required notice to the medical community (through the package insert or PDR) of the critical information contained in the more than 200 adverse-reaction reports of the incidence of cardiac and respiratory arrest, notwithstanding low dosage of Xylocaine; and (2) that physicians receiving this information would have considered it in deciding how—and whether—to

> administer Xylocaine to their patients. Resolving every inference in plaintiffs' favor, we cannot conclude that the record was devoid of the requisite minimum quantum of evidence supporting the verdict.

718 F.2d at 569 (footnote omitted).

We have earlier reviewed the specific allegations of the representative complaint in this matter regarding causation. Plaintiffs' theory is that, without Buckman's fraudulent representation, the FDA would not have given AcroMed a § 510(k) clearance and that, absent a § 510(k) clearance, AcroMed would not have access to the market to promote its devices for use in spinal surgery and plaintiffs would not have suffered injury. Given the terminology chosen, it appears to us that the district court viewed the causation standard for unintentional torts as the applicable one and regarded the yielding of plaintiffs' physicians to AcroMed's promotion as an intervening cause. It may be that plaintiffs' theory would be so viewed under the law of some jurisdictions. It is not clear to us, however, that it would be so viewed under all of the potentially applicable law. Buckman's representation to the FDA regarding intended use is alleged to have been intentional. Moreover, while it is not alleged that harm to plaintiffs was intended, plaintiffs do claim to be able to show that Buckman's representation was a necessary element of a conspiracy to get doctors to do exactly what plaintiffs' physicians did. *See, e.g., Restatement (Second) of Torts* § 435 B ("Unintended Consequences of Intentional Invasions") and § 442 B ("Intervening Force Causing Same Harm as That Risked by Actor's Conduct").

We do not hold that plaintiffs have or have not alleged a legally sufficient causal nexus. That issue can be resolved only after the controlling law has been identified in each case. We do hold that the district court erred in determining at this stage that all of the plaintiffs have failed to allege a legally sufficient causal nexus.

B.

Buckman insists that a statement of intended use in connection with a § 510(k) application is not a representation of a fact or intent but, rather, a request for authority. In its view, the sole interest of the FDA in the applicant's intended use is to enable it to limit the authority granted to that which is sought and considered by the agency. In a related argument, Buckman contends that FDA reliance on the alleged misrepresentation is "negated in this case by ... the nature of the clearances that were given to AcroMed," Buckman Br. at 23, i.e., they were limited to long bone use only.

We, of course, acknowledge that a statement of intended use in connection with a § 510(k) application has utility in communicating the authority sought and in permitting the FDA to appropriately limit any authority granted. At the same time, we believe that such a statement is a representation of fact that is necessarily important to the FDA as such.

The use to which a device will be put is of critical importance in the regulatory scheme. A device that presents no risk of injury when employed for one purpose may present great risk of injury when employed for another. For this reason a § 510(k) clearance will be issued only if a device is a substantial equivalent of a preexisting device used for the same purpose. Moreover, a device cleared under § 510(k) cannot lawfully be marketed for a use other than the use specified in the clearance. Thus, if such a device is marketed for another purpose, the manufacturer may be civilly and criminally sanctioned and the marketing enjoined. *See* 21 U.S.C. §§ 331, 332.

According to Buckman, the FDA requires no representation from a § 510(k) applicant regarding its marketing intentions and reads its representation with respect to "intended use" as no more than a description of the

authority sought. Implicit in this view is the assertion that the marketing plans of a manufacturer seeking access to the market are of no interest to the FDA. If this be taken as an assertion of fact by Buckman, it is inappropriate at this stage because it conflicts with the allegations of the complaint. Plaintiff Donald G. Patterson, for example, alleges that "Were it not for [the misrepresentations that the applicant's intended use was in repairing fractures of the long bones], the FDA would not have issued 510(k) clearances ... for any purpose, the devices would not have been introduced into interstate commerce, and Plaintiff would not have been exposed to the dangerous device which was surgically implanted in the Plaintiff's spine." App. at 63.

To the extent Buckman's argument is an assertion of law, we find no basis for it in the statute, in the regulations, or in any of the authorities cited in the briefing. To the contrary, such an assumption is fundamentally at odds with the statutory scheme. Under that scheme, the FDA is a gatekeeper charged with the responsibility of protecting the public from unreasonable risks of injury from medical devices. A manufacturer of a new device has no access to the market for any purpose absent some kind of FDA approval. Because the degree of risk presented by any device is a function of the use to which it is put, the intended use is thus a central focus in the FDA review. Indeed, there is nothing more material to its determination of whether to grant access to the market.

It is undoubtedly true, as Buckman insists, that a manufacturer unable lawfully to secure a § 510(k) clearance for one purpose may legally be entitled to a § 510(k) clearance for the same device when put to a different purpose. The allegation here, however, is that AcroMed had no lawful access to the market for any purpose and that it secured such access only by representing that it intended to market its device for one use when, in fact, it intended at the time of the application to market that device solely for

another, more hazardous use.[7] If a manufacturer in AcroMed's position is successful in its scheme, we know that, when its marketing campaign is detected postissuance, the FDA is entitled to an injunction stopping that campaign. Under Buckman's view of the law, however, if the FDA is astute enough to uncover the scheme during its review, it is powerless to deny access to the market in the first place. We decline to accept a proposition so fundamentally at odds with the agency's gatekeeping assignment.

C.

Finally, Buckman argues that on the facts alleged there was no reliance by the plaintiffs on Buckman's statement to the FDA concerning intended use. This is true. This does not, however, negate the possible existence of a claim upon which relief can be granted. As we have earlier noted, § 310 of the *Restatement (Second) of Torts* suggests that when someone makes a fraudulent misrepresentation for the purpose of inducing action by A which, if taken by A, will involve an unreasonable risk of injury to B, B may recover for resulting physical injury even though he was unaware of the fraudulent misrepresentation. It is possible that the controlling law in one or more of these cases takes a similar approach.

V.

Our holding is a narrow one. We do not hold that any of the plaintiffs have stated a claim under state law upon

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[7] The situation here alleged bears no resemblance to one in which an applicant for a § 510(k) clearance intends to market its device for the use represented, subsequently markets for that use, and, at the same time, responds to direct requests for information from physicians concerning off-label use. As a result, we do not share our dissenting colleague's concern that recognizing a statement of intended use in an application for § 510(k) clearance as a representation of the applicant's marketing intentions will chill the dissemination of information relevant to off-label use.

which relief could be granted.[8] Neither we nor the district court is in a position to do that before identifying, with the help of the parties, the governing law or laws. Rather, we hold that (1) the plaintiffs' "fraud on the FDA" theory of liability is not so at odds with traditional principles of tort law that Buckman is entitled to a dismissal of all claims against it at this stage; and (2) if the state law of fraudulent misrepresentation applicable in one or more of these cases would impose liability on Buckman in the circumstances alleged, that law would not be preempted by the MDA. The judgment of the district court will be reversed, and the case will be remanded for further proceedings consistent with this opinion.

COWEN, Circuit Judge, dissenting.

The majority endorses a claim of "fraud on the FDA" under circumstances that will expose manufacturers to fraud liability for seeking desirable innovations in a product's use, distort the penalty scheme established by the FDCA and its regulations, and generate substantial liability when manufacturers respond to doctors' widely accepted practice of purchasing medical products for off-label uses.

To appreciate how much this case departs from previous cases involving "fraud on the FDA," it is important to see what all agree is not fraud in this case. When Buckman sought approval from the FDA for using its screws on long bones, Buckman did not present any false evidence about the similarity of the screws to the already approved long bone screws, and there is no dispute that AcroMed's screws are

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[8] Nor do we hold, as suggested by the dissent, that any of the plaintiffs have stated a claim under the FDA's regulations. Plaintiffs do not purport to state such a claim and, as we have earlier explained, controlling precedent bars recognition of a private cause of action under the FDCA, the MDA, or their implementing regulations.

"substantially equivalent" to the pre-existing screws. The FDA's determination that AcroMed's screws should be approved for long-bone use has never been questioned.

The basis for the majority's conclusion that Buckman committed fraud on the FDA is that in seeking long-bone approval AcroMed and Buckman really intended to market the screws for spinal use. That is, once the screws could be sold legally for long-bone use, AcroMed planned surreptitiously to induce physicians to buy the screws for spinal use. Clearly, if AcroMed actively marketed the screws for spinal use in violation of FDA's limited approval for long-bone use, AcroMed (and Buckman to the extent it participated in the plan) would have violated the FDA's marketing rule and could be held accountable *by the FDA*. A violation of the marketing rules, however, is not fraud on the FDA; it is an ordinary transgression of an agency's regulatory rules. AcroMed and Buckman also could be held liable by doctors and, in most states, their patients if AcroMed and Buckman told doctors that the bone screws were approved by the FDA for spinal use or made other material misrepresentations. But the statements made to doctors are not the basis for the majority's theory of "fraud on the FDA." To the contrary, the majority finds fraud in Buckman and AcroMed's statement to the FDA of the intended purpose of the screws in their application for long-bone approval. It is on this point that the majority creates dangerous confusion.

The mere fact that AcroMed or Buckman really wanted approval for the spinal use of the screws does not make their request for long-bone approval fraudulent. Seeking approval for one use should not preclude a manufacturer, via the penalty of fraud liability, from seeking approval for another use for the same product. Expanding the uses for existing products will often be a very desirable source of progress and innovation in medical products. A manufacturer may even deliberately start off by seeking approval for a conventional

use while waiting to gain approval for a different, novel and potentially highly profitable use of the product. Such a strategy could have the beneficial effect of increasing competition in the market for the conventional use while at the same time providing revenue to make it easier to negotiate the arduous FDA approval process. By reading the phrase "intended use" in the application as a declaration of what the manufacturer wants ultimately to seek with the medical device, rather than simply as a request for a specific FDA approval (with nothing implied about future requests), the majority creates an interpretation that is economically unrealistic and is likely to hinder technological growth.

The legal concept that the FDA was "defrauded" because a company desired approval for a different use from the one requested and ultimately approved is particularly hard to sustain in this case. Before the FDA approved the screws for long bones, it had twice previously rejected Buckman and AcroMed's applications for spinal use. Those prior applications made unmistakably clear to the FDA that Buckman and AcroMed wanted as their first choice approval for spinal use of the screws. There was no deception about AcroMed's ultimate goals. The FDA most assuredly knew what clearance was sought and what clearance was granted or denied.

The majority may believe that what distinguishes this case from one where a company simply seeks approval for one use while really wanting approval for another (and hence what prevents this decision from flatly prohibiting innovation), is that Buckman and AcroMed obtained long bone approval allegedly with the intention of illegally marketing the screws for off-label use. Such a theory, however, stretches the "intended use" statement into an all purpose guarantee that an applicant will not violate other FDA rules. Under the majority's position the only basis for finding that AcroMed and Buckman committed fraud on the FDA is that they allegedly intended to violate the FDA's

regulations prohibiting marketing for off-label uses. It is hard to see why that is not in effect creating a private right of action for a violation of the FDA regulation, and it is difficult to reconcile that conclusion with a point the majority itself made in footnote 8: "controlling precedent bars recognition of a private cause of action under the FDCA, the MDA, or their implementing regulations." Given the demanding detail of the regulatory process, and the wide variety of violations ranging from the innocuous to the serious, recognizing a state cause of action for violations of FDA regulations will greatly distort the penalty scheme established by the statute. The penalties attached to a violation of the FDA's regulations will often be substantially increased, and enforcement of violations will no longer be controlled by the FDA's prosecutorial discretion.

The majority's position is problematic in another closely related respect. The FDA and the medical community have long recognized the importance of doctors' off-label uses of medical products (uses not indicated on the label or approved by the FDA). See James M. Beck & Elizabeth D. Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 Food & Drug L.J. 71, 72 (1998).[1]

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[1] The article explains that: "It is an accepted principle that once [the] FDA determines that a drug or device can be marketed, a physician's discretionary use of that product (the practice of medicine) is not restricted to the uses indicated on FDA-regulated labels. Off-label use is widespread in the medical community and often is essential to giving patients optimal medical care, both of which medical ethic[ists], [the] FDA, and most court recognize." BECK & AZARI, *supra*, at 72. The article points out that the FDA stated in a 1982 *Drug Bulletin* that: " 'unapproved' or more precisely 'unlabeled' uses may be appropriate and rational in certain circumstances, and may, in fact reflect approaches to drug therapy that have been extensively reported in medical literature... Valid new uses for drugs already on the market are often first discovered through serendipitous observations and therapeutic innovations ..."

Doctors may, in the exercise of their professional judgment, decide that based on current medical research an unapproved use of a product best serves a patient's needs.

Permitting off-label uses may seem anomalous given that the FDA's labeling and marketing restrictions prevent companies from actively pursuing an off-label market. Moreover, the fact that the FDA lacks authority to regulate the practice of medicine might imply that off-label uses amount to an end-run around the agency's authority. But the FDA's own position on off-label use reveals that off-label uses are a valuable part of the practice of medicine.[2] The difficulty not confronted by the majority is that there is a very real tension created between endorsing off-label uses but preventing marketing for those uses. Close questions will be raised about whether a manufacturer was simply responding to doctors' desirable demand for off-label uses, or whether a manufacturer was impermissibly trying to create an off-label market and circumvent the FDA's regulation. As matters stood before this decision, the FDA was left to police the boundary between permissible and impermissible responses to off-label demand. The majority's theory, however, now throws into the jury box the question of when unacceptable "marketing" has taken place.

BECK & AZARI, supra, at 77. With regard to bone screws in particular, the article quotes the following statement by the FDA in a 1993 publication titled *Food and Drug Administration, Update on Pedicle Screws:* "In practice, surgeons often use orthopedic screws which FDA has cleared for other purposes ... as pedicle screws. Such use of medical devices for non-approved purposes has traditionally been regulated by the hospitals in which the physicians practice and not by the FDA." BECK AND AZARI, *supra*, at 77.

[2] *See Washington Legal Foundation v. Kessler*, 880 F.Supp. 26, 28 n.1 (D.D.C. 1995), *Washington Legal Foundation v. Friedman*, No. 94-1306, 1998 WL 456372, at *3 (D.D.C. July 30, 1998) and *supra* note 1.

Consider the problem of deciding when impermissible "marketing" has taken place in manufacturer-sponsored continuing medical education ("CME"). After manufacturers began in recent years financially underwriting more CME seminars and materials, the FDA developed, in response to Congressional hearings and ensuing confusion over an FDA concept paper, a twelve-factor test to decide when a manufacturer-sponsored CME seminar violated the FDA's rules on marketing. *See Washington Legal Foundation v. Friedman*, No. 94-1306, 1998 WL 456372, *4 (D.D.C. July 30, 1998) (FDA unconstitutionally restricted commercial speech because less restrictive means of achieving the government's interest were available). As is illustrated by both the complexity of the FDA's test and its efforts to hone its response, difficult and subtle balancing is called for in evaluating manufacturers' roles in the creation and distribution of information about off-label uses of drugs and medical devices.[3] The problem is not easily dismissed. Once

[3] Recent legislation which, once effective, will supersede the FDA's restriction on distributing printed material underscores the incongruity of the majority's position. The Food and Drug Modernization Act of 1997, Pub.L. No. 105-115, 111 Stat. 2296 (to be codified at 21 U.S.C. § 360aaa, et seq.) permits manufacturers to distribute information about off-label uses of drugs and devices provided certain requirements are met. Among the requirements for a drug, for instance, is that the manufacturer must have submitted an application for approval of the new, off-label use. Thus, manufacturers are allowed to submit applications for new uses and to distribute certain information about the off-label use while an application for the off-label use is still pending. On the majority's theory, will the manufacturer have committed fraud on the FDA, notwithstanding the new statutory provisions, if the manufacturer secures approval for one use, distributes materials on off-label uses in compliance with the statute, and does so while its primary objective is to obtain approval for the off-label use pending with the FDA?

it is accepted that off-label uses are desirable, it is difficult to maintain that doctors should be shielded from truthful information concerning when and how to use a product for an off-label use. Patients will benefit by having their doctors informed about off-label uses.

Contrary to the majority's position, the problem of allowing juries to determine when a manufacturer has improperly advertised an off-label use is not only that it will impose too stringent a rule, chilling dissemination of valuable information about off-label uses; it is also that jury decisions lack the consistency of an agency-enforced rule. Even apart from the harm of restricting beneficial information about off-label uses, and the need for a consistently enforced rule wherever the line is drawn, a jury's assessment of liability is problematic in a third sense: Massive liability will be imposed where the FDA would not find any misconduct, and the cost of medical devices will be needlessly raised.

It begs the question simply to respond, as the majority does in footnote 7, that a manufacturer will not face liability when it actually markets for the "intended use" listed in the 510(k) application and answers requests for information about off-label uses. The problem remains: the majority permits liability for fraud on the FDA when a jury concludes that a manufacturer conducted impermissible marketing, demonstrating that the manufacturer "defrauded" the FDA in its statement of intended purpose. Presumably, the majority's response is not that juries' interpretations of "marketing" will pose limited problems because a manufacturer can insulate itself from liability for fraud on the FDA by the simple act of making sales for the intended use listed in the 510(k) application. That seems like a very wooden distinction, for why should those sales be so important from the standpoint of liability for fraud on the FDA? Isn't the problem illegal marketing? If the majority does not require any showing of illegal marketing, how can liability be justified? The effect of the rule will be to prohibit manufacturers from making

otherwise entirely legal responses to demand for off-label uses, responses that the FDA itself accepts as desirable. Or even worse, the rule will very directly prohibit innovation in the uses of drugs and devices by triggering fraud liability when an application is filed for approval of a new use. Once it is admitted that the majority's theory focuses on illegal marketing, we are thrown back on all the problems listed above.

Nowhere does the majority demonstrate the need for its new theory of fraud on the FDA. The plaintiffs can be adequately compensated by their doctors under existing law for any malpractice demonstrated; the defendants can be held liable for fraud if they told doctors they had FDA approval that they did not; and the FDA remains free to prosecute when it feels impermissible marketing has taken place. Manufacturers also can be held liable under product liability law.

In sum, when juries are permitted to displace the FDA's judgment about whether a manufacturer has engaged in improper marketing, they will fail to provide a consistent standard, inhibit valuable exchange of information on off-label uses, and needlessly raise the price of drugs and medical devices. It seems very unlikely that Congress intended a state cause of action to intrude so much both in the enforcement of the FDCA's regulatory scheme and in the severity of the penalties attached to a violation.

I most respectfully, but vehemently, dissent.

APPENDIX B

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: ORTHOPEDIC BONE SCREW
PRODUCTS LIABILITY LITIGATION

MDL DOCKET NO. 1014

THIS DOCUMENT RELATES TO ALL ACTIONS

MEMORANDUM AND ORDER

BECHTLE, J. MARCH 28, 1997

Presently before the court is the Sofamor-Danek Defendants' ("defendants") Motion to Reaffirm PTO 12 in Light of *Medtronic, Inc. v. Lohr* and, Alternatively, for Summary Judgment Against Claims Alleging Fraud an the FDA[1] ("Motion to Reaffirm PTO 12") and plaintiffs' response thereto.[2] For the reasons set forth below, the court will grant the motion inasmuch as the reasoning of Pretrial

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[1] "FDA" refers to the Food and Drug Administration.

[2] On February 6, 1997, defendants withdrew without prejudice the portion of their motion requesting summary judgment. Accordingly, the court will address only the portion requesting reaffirmation of Pretrial Order No. 12's dismissal of plaintiffs' fraud-on-the-FDA claims.

Order No. 12 rests on the absence of an implied private right of action for violations of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.* ("FDCA") and deny the motion inasmuch as the reasoning of Pretrial Order No. 12 rests on the doctrine of preemption. Also before the court is defendant Advanced Spine Fixation Systems, Inc. *et al.*'s (also "defendants")[3] Motion to Dismiss Fraud on the FDA, Intracompany Conspiracy, and Liability *per se* Claims Made in Amended Omni Complaints ("Motion to Dismiss")[4] and plaintiffs' response thereto. For the reasons set forth below, the court will grant the portion of the motion requesting the dismissal of plaintiffs, fraud-on-the-FDA claim. The remaining claims for which defendants seek dismissal will be addressed in a separate Memorandum and Order.

I. BACKGROUND

On March 2, 1995, this court entered an Order dismissing plaintiffs' fraud-on-the-FDA claims stating, among other things, that those claims were preempted by the Medical Device Amendments of 1976 ("MDA"), which amended the FDCA. *See* Pretrial Order No. 12 at 4. On June 26, 1996, the United States Supreme Court rendered its decision in *Medtronic, Inc. v. Lohr*, 116 S. Ct. 2240 (1996), holding that the MDA does not preempt a state common-law negligence action against the manufacturer of an allegedly defective medical device. Defendants now seek to have this court reaffirm Pretrial Order No. 12 in light of *Lohr*.

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[3] The other moving defendants are Robert Howland, Leon Wiltse, M.D., Curtis Spencer III, M.D., and James Thomas, Jr., M.D.

[4] Defendants' Form of Order refers to the motion as "Motion to Dismiss Fraud on the FDA, Intracompany Conspiracy, Fraudulent Marketing and Promotion, and Liability *per se* Claims Made in Amended Omni Complaints." However, the memorandum in support of the motion does not address fraudulent marketing and promotion.

II. DISCUSSION

The court recognizes that it has a "strong duty to decide a case on nonconstitutional grounds whenever possible," *Williams v. School Dist. of Bethlehem*, 998 F.2d 168, 176 (3d Cir. 1993), *cert. denied*, 510 U.S. 1043 (1994), and that "as a matter of established federal jurisprudence ... a court faced with both constitutional and nonconstitutional claims must address the nonconstitutional claims first, if doing so will enable the court to avoid a constitutional confrontation." *Erie Telecomms., Inc., v. City of Erie*, 853 F.2d 1084, 1092-93 (3d Cir. 1988). However, because the motion before the court requests reaffirmation of Pretrial Order No. 12 in light of *Lohr*, and because the court's reasoning in Pretrial Order No. 12 did partly rest on the doctrine of preemption, the court will address the effect of the *Lohr* decision on this court's dismissal of plaintiffs' fraud-on-the-FDA claims on both constitutional and nonconstitutional grounds.

A. Motion to Reaffirm PTO 12

Plaintiffs argue that an FDA regulation and a federal statute requiring truthfulness may serve as the standard of care in a state common-law claim and cite a number of cases in support of this proposition. Plaintiffs point to two provisions which they believe should serve as the standard of care in their state common-law claims — 21 C.F.R. § 807.87(j),[5] which requires that each premarket notification

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[5] 21 C.F.R. § 807.87 provides in pertinent part:

> Each premarket notification submission shall contain the following information: ...
>
> (j) A statement that the submitter believes, to the best of his or her knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

submission contain a statement that the submitter believes the premarket notification to be truthful, and 18 U.S.C. § 1001,[6] which makes it a crime to make fraudulent statements to government agencies. Plaintiffs seek to hold defendants liable for violations of these two provisions. Plaintiffs at the same time assert that their fraud-on-the-FDA claim does not invoke the doctrine of negligence per se, although most of their brief argues in favor of this. (Pls.' Mem. Opp'n at 53.) Regardless, the issue before the court is whether *Lohr* now allows plaintiffs' fraud-on-the-FDA claim to go forth. The court holds that it does not. While *Lohr* may have affected the portion of Pretrial Order No. 12 that relied on the doctrine of preemption, the portion of the court's reasoning based on the absence of an implied private right of action remains in tact.

1. Private Right of Action

In Pretrial Order No. 12, the court was primarily guided by *Michael v. Shiley*, 46 F.3d 1316, 1329 (3d Cir.), *cert. denied*, 116 S. Ct. 67 (1995), in which the Third Circuit squarely held that a private party's fraud-on-the-FDA claim would not lie. The *Michael* court reasoned that "permitting a fraud claim based upon false representations to the FDA would conflict with (Third Circuit) precedent that plaintiffs may not bring implied causes of action for violations of the Food, Drug, and Cosmetic Act." *Michael*, 46 F.3d at 1329;

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[6] 18 U.S.C. § 1001 provides:

> Whoever, in any matter within the jurisdiction of any department or agency of the United States knowingly and willfully falsifies, conceals or covers up by any trick, scheme, or device a material fact, or makes any false, fictitious or fraudulent statements or representations, or makes or uses any false writing or document knowing the same to contain any false, fictitious or fraudulent statement or entry, shall be fined under this title or imprisoned not more than five years, or both.

accord Gile v. Optical Radiation Corp., 22 F.3d 540, 544 (3d Cir.), *cert. denied*, 115 S. Ct. 429 (1994); *Sandoz Pharms. Corp. v. Richardson-Vicks., Inc.*, 902 F.2d 222, 231 (3d Cir. 1990). Indeed, in view of the FDA's exclusive prosecutorial discretion under 28 U.S.C. § 337(a), any grant of an implied private right of action would be contrary to the letter and spirit of the statute.[7] *See Lohr*, 116 S. Ct. at 2251 (four-justice plurality) (stating "there is no explicit private cause of action against manufacturers contained in the MDA, and no suggestion that the Act created an implied private right of action"). Other circuits also conclude that no private right of action for violations of the FDCA exists. *See, e.g., Bailey v. Johnson*, 48 F.3d 965, 966-68 (6th Cir. 1995); *Rodriguez v. SK&F Co.*, 833 F.2d 8, 9 (1st Cir. 1987); *Fiedler v. Clark*, 714 F.2d 77, 79 (9th Cir. 1983); *Pacific Trading Co. v. Wilson & Co.*, 547 F.2d 367, 370 (7th Cir. 1976); *see also Griffin v. Medtronic, Inc.*, 82 F.3d 79, 83 n.4 (4th Cir. 1996) ("Of course, Griffin[']s claim might also be premised on the notion that Medtronic did not adequately comply with FDA disclosure requirements. However, the FDA alone is empowered to enforce its regulations. A private right of action seeking enforcement of FDA regulations has not been recognized."), *vacated*, No. 96-603, 1997 WL 63815 (U.S. Feb. 18, 1997).[8]

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[7] Section 337(a) provides, in pertinent part:

> Except as provided in subsection (b) of this section, all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States.

21 U.S.C. § 337(a).

[8] In *Griffin*, plaintiff brought five counts against Medtronic, Inc., the manufacturer of plaintiff's failed pacemakers:

(1) negligent design and manufacture;

(2) breach of express warranty;

At least one trial court, however, does not agree. In *Hawkins v. Upjohn Co.*, 890 F. Supp. 609 (E.D. Tex. 1994), the Eastern District of Texas held that under Texas law plaintiffs, conspiracy-to-commit-fraud-on-the-FDA claim stated a claim upon which relief could be granted. *Hawkins*, 890 F. Supp. at 611-12. The *Hawkins* court reasoned that plaintiffs' claim was not based on a violation of the FDCA, but was a common-law fraud claim, and therefore the fact that the FDCA did not create a private right of action was irrelevant. *Id.* at 611. Clearly, the Third Circuit when it decided *Michael*, which post-dated *Hawkins*, was not bound or persuaded by the *Hawkins* decision and neither is this court now. To give credence to the *Hawkins* holding would be to

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(3) breach of implied warranty of fitness for a particular purpose;

(4) strict liability for defective manufacture; and

(5) intentional misrepresentation of the defective condition of the pacemakers.

Griffin, 62 F.3d at 81. The trial court held that all of plaintiff's claims were preempted. *Id.* The Court of Appeals for the Fourth Circuit affirmed the trial court's ruling on plaintiff's claims of breach of implied warranty, strict liability, negligence, and intentional misrepresentation, and remanded plaintiff's express warranty claim. *Id.* at 83. The Supreme Court vacated the Fourth Circuit's decision stating:

> The judgment is vacated and the case is remanded to the United States Court of Appeals for the Fourth Circuit for further consideration in light of *Medtronic, Inc. v. Lohr* ....

Griffin, 1997 WL 63815. Because the intentional misrepresentation claim actually considered by the *Griffin* court was based on defendant's alleged failure to disclose information to plaintiff and her doctor as opposed to the FDA, the Supreme Court's ruling in *Griffin* does not affect the court's reasoning as to the instant plaintiffs' fraud-on-the-FDA claims.

allow a plaintiff who was clever enough to craft his or her complaint to plead a state common-law cause of action based on alleged wrongs committed against a federal agency to create a private right of action where one did not exist. It appears that in *Hawkins*, the dispositive factor should not have been whether plaintiffs relied on a federal statute to pursue their state common-law claim of conspiracy to commit fraud on the FDA, but rather the fact that the object of the alleged fraud was the FDA, a federal agency with exclusive prosecutorial discretion.

In support of their position, plaintiffs argue that because there are pre-*Lohr* cases which have allowed a violation of the FDCA to establish negligence per se or to establish a rebuttable resumption of negligence, that their fraud-on-the-FDA claim should lie. Plaintiffs cite *Orthopedic Equip. Co. v. Eutsler*, 276 F.2d 455 (4th Cir. 1960) and *Stanton v. Astra Pharm. Prods. Inc.*, 718 F.2d 553 (3d Cir. 1983) for the proposition that a finding of negligence may be premised on a manufacturer's FDA-created duties not to misbrand products or submit reports of all unexpected adverse reactions to a drug to the FDA. However, these cases are distinguishable from the instant one.

In these two cases where a finding of negligence was premised on a violation of an FDA regulation, the regulation in question was one whose very purpose was to ensure safety. When the FDA explicitly prohibits misbranding or explicitly requires the resorting of adverse reactions to a drug, it is directly regulating public safety; it is pursuing the goals for which it was created, which is to ensure public safety, not to ensure the absence of fraud against it. *See Lohr*, 116 S. Ct. at 2245 (quoting the MDA's preamble and stating that Congress enacted the MDA "to provide for the safety and effectiveness of medical devices intended for human use"). The tangential and albeit necessary "requirement" or "duty" or "standard of care" that one be truthful to a government agency, does not emanate from the purpose of the FDCA; it

need not be measured against a regulation prohibiting it. Hence, to label the regulations that plaintiffs cite as the "standard of care" in order to establish a cause of action for fraud on the FDA is ineffective.

2. Preemption

In addition, plaintiffs argue that *Lohr* effectively nullifies the court's ruling in Pretrial Order No. 12. This is only partially correct. While as a general matter *Lohr* established that very few state common-law causes of action are preempted by the MDA, thus invalidating the court's reliance on the doctrine of preemption as a basis for its dismissal of plaintiffs' fraud-on-the-FDA claim, it did not address claims of fraud on the FDA with respect to the absence of a private right of action for violations of the FDCA, which is one of the primary operative impediments to the instant claim's survival.

Lohr held that the MDA does not preempt a state common law negligence action against the manufacturer of an allegedly defective medical device. In the instant case, plaintiffs' fraud-on-the-FDA claim is not interchangeable with the Lohrs' negligence claim. This is so not because a state common-law fraud claim is preempted by the MDA, but because the fraud claim at issue here has as its object the FDA and not plaintiffs. That object transforms an otherwise simple fraud claim that would not be preempted by the MDA according to the reasoning of Lohr into one that is precluded by virtue of the fact that the MDA does not provide for a private right of action. Hence, *Lohr* established that the doctrine of preemption would be an inappropriate ground upon which the court should dismiss plaintiffs' fraud-on-the-FDA claim, but it did not otherwise alter the court's ruling in Pretrial Order No. 12.

B. Motion to Dismiss

Well apart from the questions of whether plaintiffs' fraud-on-the-FDA claim may go forward as an implied private right of action or whether the claim survives preemption, in isolation plaintiffs' claim is not colorable in that it does not pass Federal Rule of Civil Procedure 12(b)(6) muster. Taking all well-pleaded allegations as true and construing the complaint in the light most favorable to the plaintiffs, the court finds that under no reasonable reading of the pleadings, are plaintiffs entitled to relief for the alleged fraud committed on the FDA because the alleged fraud cannot be said to have been a proximate cause of plaintiffs' alleged injuries. *See Colburn v. Upper Darby Township*, 838 F.2d 663, 665-66 (3d Cir. 1988), *cert. denied*, 489 U.S. 1065 (1989). Legal causation largely fails because the object of plaintiffs' fraud-on-the-FDA claim is the FDA and not the doctors who performed the surgeries on plaintiffs or plaintiffs themselves. Plaintiffs allege that defendants' fraud caused the FDA to issue its 510(k) clearance[9] for the bone screws in question, which allowed the screws to be introduced into interstate commerce, which allowed doctors to exercise their judgment and implant them in plaintiffs' spines, which allowed some plaintiffs to suffer injury. The causal connection between the alleged fraud committed on the FDA and plaintiffs' alleged injuries is so tenuous, if existent at all, that the former can not be said to be a "substantial factor" in causing the latter. *Stanton*, 718 F.2d at 565; *Edward J. DeBartolo Corp. v. Coopers & Lybrand*, 928 F. Supp. 557,

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[9] "510(k) clearance" refers to the FDA's determination that the bone screws in question are "substantially equivalent" to a bone screw that was commercially distributed before the enactment of the MDA and therefore need not receive premarket approval from the FDA prior to being marketed or sold. *See* 21 U.S.C. §§ 360c(a)(1)(C), 360c(f)(3), 360c(i)(1)(A), 360e; 21 C.F.R. § 807.81 - 807.100.

563 (W.D. Pa. 1996); Restatement (Second) of Torts § 431. Thus, because "it appears beyond doubt" that plaintiffs "can prove no set of facts in support of [their] claim which would entitle [the]m to relief," even if *Lohr* theoretically would allow a private right of action for a fraud-on-the-FDA type of claim to go forward contrary to *Michael*, the court would still be compelled to dismiss it. *See Conley v. Gibson*, 355 U.S. 41, 45 (1957).

III. CONCLUSION

For the reasons stated above, the court will grant in part and deny in part Sofamor-Danek defendants' motion to Reaffirm PTO 12 and grant in part defendant Advanced Spine Fixation Systems, Inc. *et al.*'s Motion to Dismiss.

An appropriate Order follows.

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: ORTHOPEDIC BONE SCREW
PRODUCTS LIABILITY LITIGATION

MDL DOCKET NO. 1014

THIS DOCUMENT RELATES TO ALL ACTIONS

PRETRIAL ORDER NO. 845

AND NOW, TO WIT, this 28th day of March, 1997, upon consideration of Sofamor-Danek Defendants' Motion to Reaffirm PTO 12 in Light of *Medtronic, Inc. v. Lohr* and, Alternatively, for Summary Judgment Against Claims Alleging Fraud on the FDA (docket # 5103), and plaintiffs' response thereto, IT IS ORDERED that said motion is GRANTED in part and DENIED in part.

Upon consideration of Sofamor-Danek Defendants' Motion to Substitute Their Motion to Reaffirm PTO 12 for AcroMed Corporation's Motion to Reaffirm PTO 12 (docket # 5160), IT IS ORDERED that said motion is DISMISSED as moot pursuant to the instant Order.

Upon consideration of plaintiffs' Motion to Strike the Motion of the Sofamor-Danek Defendants to Reaffirm PTO 12 in Light of *Medtronic, Inc. v. Lohr* and, Alternatively, for Summary Judgment Against Claims Alleging Fraud on the FDA (docket # 5121), IT IS ORDERED that said motion is DISMISSED as moot pursuant to Pretrial Order No. 759, ¶ 12.

Upon consideration of defendant AcroMed Corporation's Motion to Reaffirm PTO 12 in Light of *Medtronic,. Inc, v. Lohr* (docket # 4814), IT IS ORDERED that said motion is GRANTED in part and DENIED in part for the reasons set forth in the accompanying memorandum.

Upon consideration of defendant Advanced Spine Fixation Systems, Inc. *et al.*'s Motion to Dismiss Fraud on the FDA, Intracompany Conspiracy, and Liability *per se* Claims Made in Amended Omni Complaints (docket # 4950) and plaintiffs' response thereto, IT IS ORDERED that the portion of the motion requesting the dismissal of plaintiffs' fraud-on-the-FDA claim is GRANTED.

/s/ LOUIS C. BECHTLE, J.

APPENDIX C

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: ORTHOPEDIC BONE SCREW
PRODUCTS LIABILITY LITIGATION

MDL DOCKET NO. 1014

THIS DOCUMENT RELATES TO ALL ACTIONS

PRETRIAL ORDER NO. 900

AND NOW, TO WIT, this 12th day of May, 1997, upon consideration of defendant Buckman Company's Motion to Dismiss Amended Omni Complaint for Failure to State a Claim Upon Which Relief May Be Granted (docket # 4943), and the opposition thereto, IT IS ORDERED that said motion is GRANTED for the reasons stated in Pretrial Order No. 845.

/s/ LOUIS C. BECHTLE J.

APPENDIX D

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: ORTHOPEDIC BONE SCREW
PRODUCTS LIABILITY LITIGATION

MDL DOCKET NO. 1014

THIS DOCUMENT RELATES TO ALL ACTIONS

ALICE and ANGELO ZAMPIRRI, *et al.*

v.

ACROMED CORPORATION, *et al.*

MEMORANDUM AND ORDER

BECHTLE, J. MARCH 2, 1995

Presently before the court is defendants Acromed Corporation and Dr. Arthur Steffee's (collectively "Acromed defendants") motion for partial judgement on the pleadings, and the *Zampirri* plaintiffs[1] response thereto.[2] For the reasons

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[1] The *Zampirri* plaintiffs' action was consolidated in the Eastern District of Pennsylvania, prior to this case being converted into a multi-district litigation, under the caption *Zampirri et al. v. Acromed*, et al., C.A. No. 93-7074. The *Zampirri* plaintiffs are: Alice and Angelo Zampirri; Margaret and Thomas Thatcher; Joanne and William Watson; Tom and Anita O'Brian; Charles and Kathryn DiRaimondi; Cale Gillette; Vivian Tyson; and Agnes Batezel.

[2] The court has also received the Acromed defendants' reply memorandum in support of its motion; plaintiffs' sur reply memorandum in opposition to defendants' motion for partial judgment on the pleadings; defendants' citation of supplemental authorities relating to its motions for partial judgment on the

set forth below, the Acromed defendants' motion will be granted.

I. INTRODUCTION

This is a products liability action for damages and equitable relief stemming from injuries allegedly suffered by plaintiffs as a result of the surgical implantation of spinal fixation devices into the pedicles of their spines.[3] On August 4, 1994, the Judicial Panel on Multidistrict Litigation converted this action into a multidistrict litigation, transferring all federal pedicle screw cases to this court for coordinated pretrial proceedings pursuant to 28 U.S.C. § 1407.[4]

The instant motion for partial judgment on the pleadings under Federal Rule of Civil Procedure 12(c) seeks to dismiss the prejudice Counts V, VI and VII of the *Zampirri* plaintiffs' amended and consolidated compliant. Count V charges the Acromed defendants with defrauding the Food and Drug Administration ("FDA"). Count VI charges the Acromed defendants with a violation of the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1964(c), ("RICO"). Count VII asserts a claim for damages against all defendants under the Lanham Act, 15 U.S.C. § 1125(a). Count VII will be dismissed by way of the attached Order, however, because, as plaintiffs concede in their memorandum of law in opposition to defendants' motion for partial judgement on the pleadings, they lack standing to pursue a Lanham Act claim.

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pleadings and partial summary judgement; and plaintiffs' reply to defendants' citation of supplemental authorities.

[3] For a thorough recitation of the facts and procedural history of this case, see the court's February 22, 1995 Memorandum and Order, Pretrial Order No. 8.

[4] On February 22, 1995, the court denied the *Zampirri* plaintiffs' motion for class certification. *See* Pretrial Order No. 8.

II. LEGAL STANDARD

Federal Rule of Civil Procedure 12(c) permits a motion for judgment on the pleadings to be made after the pleadings are closed. Fed. R. Civ. P. 12(c). Under Rule 12(c), judgment on the pleadings is proper when the moving party clearly establishes on the face of the pleadings that no material issue of fact remains to be resolved and that it is entitled to judgment as a matter of law. *See McMann v. Phoenix Home Life Mutual Ins. Co.*, No. CIV.A. 94-2229, 1994 WL 410770, at *1 (E.D. Pa. Aug. 4, 1994). When deciding whether to grant a Rule 12(c) motion, the court must view the facts in the light most favorable to the non-moving party. *See Institute for Scientific Information, Inc. v. Gordon and Breach, Science Publishers, Inc.*, 931 F.2d 1002, 1005 (3d Cir.), *cert. denied*, 502 U.S. 909 (1991).

III. DISCUSSION

A. Count V - Fraud on the FDA

In paragraph 107 of their amended and consolidated complaint, the *Zampirri* plaintiffs allege that the Acromed defendants "intentionally, knowing and/or recklessly" misled the FDA when Acromed applied for premarket approval of its nested bone plates and cancellous bone screws. Plaintiffs assert that defendants' fraud on the FDA caused plaintiffs to suffer personal injuries for which there is a private right of action under principles of state law. The Acromed defendants argue that plaintiffs' fraud on the FDA claim should be dismissed because it is preempted by federal law.[5]

[5] Pursuant to the parties' joint Report on Summary Judgment Motions on Preemption, filed with the court on February 28, 1995, the court notes that by way of this Memorandum and Order, the only preemption issue it will resolve at this time is whether a fraud on the FDA claim is preempted by federal law.

Under the law of the Third Circuit, plaintiffs' fraud on the FDA claims against the Acromed defendants must be dismissed because plaintiffs' claims are preempted under the medical device amendments to the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360k ("FDCA"). *See Michael v. Shiley, Inc.*, No. CIV.A. 94-1496, 1995 WL 45034 (3d Cir. February 7, 1995). In *Michael*, a case with facts similar to the present case, the plaintiff brought negligence, strict product liability, breach of implied warranty of merchantability, breach of express warranty, and common law fraud claims against the manufacturer of a heart value. *See id.* at *1-2. The Third Circuit dismissed plaintiff's fraud on the FDA claims, stressing that section 360k of the medical device amendments to the FDCA does not permit courts to "perform the same function initially entrusted to the FDA." *Id.* at *12. Because the FDA possesses the proper authority to regulate this field, courts are prohibited from conducting "a searching state inquiry into the inner workings of FDA procedures." *Id.*

Plaintiffs argue that *Michael* is distinguishable from the present action and should not control this court's decision on preemption because the Class III medical devices in *Michael* were approved through the FDA's premarket approval process unlike Acromed's Class II bone screws and bone plates which were approved through the "less stringent" FDA premarket notification process. Plaintiffs contend that the preemption of claims relating to medical devices cannot apply to those devices which have not received premarket approval from the FDA. The court, however, disagrees and follows the Fifth Circuit's reasoning in *Reeves v. Acromed Corp.*, No. CIV.A. 93-3752, 1995 WL 29058, at *5 (Feb. 10, 1995), that plaintiffs' "attempt to distinguish this case on the basis of the type of FDA approval process at issue is unpersuasive." In reaching its decision, the *Reeves* court stressed:

> [e]ven if the FDA's Pre-Market Notification process does not result in the FDA's "official approval" of a device,

> the agency subjects the manufacturer's proposed labeling to extensive scrutiny....FDA regulations required AcroMed to submit its proposed labeling with its Pre-Market Notification application. *See* 21 C.F.R. § 807.87(e). The regulations also required the FDA to review AcroMed's labeling to ensure that it was in compliance with the general labeling regulations set out in 21 C.F.R. §§ 801 *et seq*. Therefore, despite the difference between the FDA's Pre-Market Approval and Pre-Market Notification procedures, our preemption analysis remains the same.[6]

Id. As the *Reeves* court stated, "[g]iven the FDA's central role in reviewing and approving devices under the [medical device amendments], the FDA is in the best position to decide whether AcroMed withheld material information from the agency and, if so, the appropriate sanction." *Id*. at *7.

Finally, "permitting a fraud claim based on false representations to the FDA would conflict with [Third Circuit] precedent that plaintiffs may not bring implied causes of action for violations of the Food, Drug and Cosmetic Act." *Michael*, 1995 WL 45034 at *12 (*citing Gile v. Optical Radiation Corp.*, 22 F.3d 540, 544 (3d Cir.), *cert. denied*, 115 S. Ct. 429 (1994). Thus for the reasons stated in both *Michael* and *Reeves*, the *Zampirri* plaintiffs' fraud on the FDA claims against the Acromed defendants will be dismissed. *See also, King v. Collagen Corp.*, 983 F.2d 1130, 1139-40 (1st Cir. 1993).[7]

---

[6] The court emphasize that by way of this Memorandum and Order, it is not at this time determining whether the scope of preemption for any issue other than fraud on the FDA is the same for Class II and Class III medical devices.

[7] In *Reeves*, the Fifth Circuit noted that the First Circuit, in *King v. Collagen Corp.*, 983 F.2d 1130, 1136, 1139-40 (1st Cir. 1993), is the only other circuit court that has "specifically address[ed] whether evidence of fraud on the FDA is sufficient to defeat preemption under § 360k" of the medical device amendments of the FDCA. *Reeves*, 1995 WL 29058, at *6. In *King*, the First Circuit held that federal law preempted a plaintiff's claim that the manufacturer of a product fraudulently withheld vital safety information from the FDA during the FDA's approval process. 983 F.2d at 1136, 1139-40.

B. Count VI - RICO

Count VI of the *Zampirri* plaintiffs' amended and consolidated complaint charges the Acromed defendants with RICO violations. Paragraph 120 of plaintiffs' complaint asserts that as a result of the Acromed defendants' pattern of racketeering activity, plaintiffs sustained injuries because they "paid excessive amounts" for Acromed's VSP system devices, did not get the pedicle screw system they bargained for, and "incurred [the] additional cost and expense of continued medical treatment." Plaintiffs seek to recover damages for their injuries under the private treble damage remedy provisions of the RICO statute, 18 U.S.C. § 1964(c).

Acromed argues that plaintiffs cannot recover under RICO for their alleged injuries because the RICO statute does not authorize recovery for the types of injuries alleged.

As plaintiffs themselves concede, the RICO statute does not permit recovery of damages for personal injuries. *See* 18 U.S.C. § 1964(c). By its express terms, RICO provides for recovery only for "any person injured in his business or property." 18 U.S.C. § 1964(c). *See Genty v. Resolution Trust Corp.*, 937 F.2d 899, 918-19 (3d Cir. 1991) ("RICO plaintiffs may recover damages for harm to business and property only, not physical and emotional injuries due to harmful exposure to toxic waste."). The court finds that the medical expenses allegedly incurred by plaintiffs are so closely tied to their alleged personal injuries that such expenses cannot be recovered under RICO. *See id*. *See also*,

Doe v. Roe, 958 F.2d 763, 767-68 (7th Cir. 1992); *Grogan v. Platt*, 835 F.2d 844, 846-47 (11th Cir.), *cert. denied*, 488 U.S. 981 (1988). Accordingly, Count VI of plaintiffs' complaint will be dismissed.

IV. CONCLUSION

For the foregoing reasons, the court will grant the Acromed defendants' motion for partial judgment on the pleadings under Federal Rule of Civil Procedure 12(c).

The court rules that the attached Order governs all actions included in MDL 1014 and dismisses all fraud on the FDA, RICO, and Lanham Act claims contained in any such pleading, and it grants any motion currently seeking dismissal of such claims in all MDL 1014 actions.

Currently there are approximately 135 separate actions, representing claims of multiple plaintiffs, included in the MDL 1014 multidistrict litigation. The court has not examined all of those complaints. The court, therefore, bases its present ruling on the understanding that all of the actions and the claims included in MDL 1014 are substantially similar to the action filed by the *Zampirri* plaintiffs, in that the plaintiffs are individuals seeking damages directly or indirectly, primarily for personal injuries allegedly resulting from the surgical implantation of spinal fixation devices into the pedicles of persons identified in each plaintiff's complaint. Any plaintiff whose claim is not of this nature and who believes that the grounds for dismissal relied on by the court in this Memorandum do not apply, may file within fifteen (15) days of the date of this Order, through the Plaintiffs' Legal Committee, a motion for reconsideration setting forth, in fact-specific allegations, how his or her claim differs from that alleged in the *Zampirri* complaint in respect to the criteria the court relied on in making its present ruling supporting the dismissals of three of the *Zampirri* claims.

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: ORTHOPEDIC BONE SCREW
PRODUCTS LIABILITY LITIGATION

MDL DOCKET NO. 1014

THIS DOCUMENT RELATES TO ALL ACTIONS

ALICE AND ANGLEO ZAMPIRRI, *et al.*

v.

ACROMED CORPORATION, *et al.*

PRETRIAL ORDER NO. 12

ORDER

AND NOW, TO WIT, this 2nd day of March, 1995, upon consideration of defendants Acromed Corporation and Dr. Arthur Steffee's (collectively the "Acromed defendants") motion for partial judgment on the pleadings under Federal Rule of Civil Procedure 12(c), and the *Zampirri* plaintiffs' response thereto, IT IS ORDERED that the Acromed defendants' motion is *granted*.

This Order hereby dismisses all fraud on the FDA, RICO, and Lanham Act claims contained in any pleading, and grants any motion currently seeking dismissal of such claims in all MDL 1014 actions, *except* any action that qualifies for reconsideration, *provided* a motion for reconsideration is filed with the court, in accordance with the court's accompanying Memorandum, within fifteen (15) days of the date of this Order.

/s/ LOUIS C. BECHTLE, J.

APPENDIX E

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: ORTHOPEDIC BONE SCREW
PRODUCTS LIABILITY LITIGATION

THIS DOCUMENT RELATES TO ALL ACTIONS

MDL DOCKET NO. 1014

PRETRIAL ORDER NO. 106

FINAL JUDGMENT ORDER PURSUANT TO FED.R.CIV.P. 54(b)

AND NOW, this 12th day of September, 1997 upon consideration of Plaintiffs' Motion for Clarification of PTO 900 and for Certification and Entry of a Final Judgment Pursuant to *Fed.R.Civ.P.* 54(b) Dismissing Plaintiffs' Claims Against Defendant Buckman Company Asserted in the Amended "Omni" Complaints and Plaintiffs' Motion for Certification for Immediate Interlocutory Appeal under 28 *U.S.C.* § 1292(b) of Certain Issues Decided in Pretrial Order No. 845, it is hereby

ORDERED, ADJUDGED and DECREED that Plaintiffs' Motion for Clarification of PTO 900 and for Certification and Entry of a Final Judgment Pursuant to *Fed.R.Civ.P. 54(b)* Dismissing Plaintiffs' Claims Against Defendant Buckman Company Asserted in the Amended "Omni" Complaints is GRANTED in part and DENIED in part. The portion of the motion requesting clarification is denied. The portion of the motion requesting final judgment is granted.

IT IS FURTHER ORDERED that the dismissal of the fraud-on-the-FDA claims against Buckman Company ("Buckman") in the amended "Omni" complaints by PTO

900, which refers to and is based on PTO 845, is certified as a final judgment pursuant to *Fed.R.Civ.P.* 54(b) because:

a. The only claims brought against Buckman are claims for fraud-on-the-FDA;

b. in the context of this multidistrict litigation, consisting of approximately 2,300 individual civil actions involving 5,041 plaintiffs suing 334 defendants in 85 districts in 46 states, where hundreds of plaintiffs have brought claims against Buckman and other defendants alleging fraud-on-the-FDA, which the Court dismissed in Pretrial Order Nos. 845 and 900, there is no just reason to delay appeal of this decision dismissing plaintiffs' claim of fraud-on-the-FDA from the litigation;

c. the dismissal of defendant Buckman from the litigation due to the dismissal of plaintiffs' fraud-on-the-FDA claims for the reasons stated in PTO 845 presents a controlling issue of law which. if erroneous, would constitute reversible error on final appeal;

d. the final adjudication of the viability of plaintiffs' fraud-on-the-FDA claims by the Third Circuit Court of Appeals, prior to remand of these hundreds of cases to their transferor districts, as opposed to final adjudication by numerous different Circuit Courts of Appeals, is the best means of achieving the goals of efficient and uniform adjudication of numerous actions for the reasons set forth in *Curtiss-Wright Corp. v. General Electric Co.*, *446* U.S. 1 (1980) and *In re Food Lion, Inc., Fair Labor Standards Act Litig.*, 73 F.3d 528, 533 (4th Cir. 1996), and will materially advance the termination of this multidistrict litigation;

e. the final adjudication of plaintiffs' fraud-on-the-FDA claim is separate, distinct and independent of the claims for design defect, manufacturing defect, failure to warn, breach of warranties, misrepresentation, negligence *per se* and

conspiracy and concert of action remaining in the litigation against remaining defendants;

f. review of this decision by the Third Circuit will not be mooted by any future developments in the case; and

g. no appellate court would have to decide this same issue more than once even if there were subsequent appeals.

The Clerk of the Court is hereby directed to enter a final judgment dismissing plaintiffs' fraud-on-the-FDA claims against Buckman alleged in the amended "Omni" complaints and thereby dismissing Buckman from the litigation.

IT IS FURTHER ORDERED that in light of the above ruling, Plaintiffs' Motion for Certification For Immediate Interlocutory Appeal under 28 *U.S.C.* §1292(b) of Certain Issues Decided in Pretrial Order No. 845 is hereby **DISMISSED as MOOT**.

/s/ LOUIS C. BECHTLE, J.

APPENDIX F

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 97-1783

IN RE: ORTHOPEDIC BONE SCREW PRODUCTS LIABILITY LITIGATION

Plaintiffs Legal Committee, Appellant

SUR PETITION FOR REHEARING

BEFORE: BECKER, *Chief Judge,* SLOVITER, STAPLETON, MANSMANN, GREENBERG, SCIRICA, NYGAARD, ALITO, ROTH, LEWIS, McKEE, RENDELL AND COWEN,* *Circuit Judges*

The petition for rehearing filed by petitioner in the above-entitled case having been submitted to the judges who participated in the decision of this court and to all the other available circuit judges of the circuit in regular active service, and no judge who concurred in the decision having asked for rehearing, and a majority of the circuit judges of the circuit in regular active service not having voted for rehearing by the court en banc, the petition for rehearing is denied. For the reasons set forth in his dissent, Judge Cowen would have granted panel rehearing.

* Hon. Robert E. Cowen, U.S. Circuit Judge for the Third Circuit, assumed senior status before the filing of the petition for rehearing; consequently, his vote is limited to panel rehearing only.

By the Court,

_____

Circuit Judge

DATED: Feb. 03, 1999

APPENDIX G

21 U.S.C. § 360k

§ 360k. State and local requirements respecting devices

(a) General rule

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

(b) Exempt requirements

Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if—

(1) the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or

(2) the requirement—

(A) is required by compelling local conditions, and

(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.

(3)

No. 98-1768

Supreme Court, U.S.
FILED
JUN 1 1999
CLERK

In the Supreme Court of the United States

OCTOBER TERM, 1998

THE BUCKMAN COMPANY,

Petitioner,

v.

PLAINTIFFS' LEGAL COMMITTEE,

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Third Circuit

BRIEF IN OPPOSITION TO PETITION FOR A WRIT OF CERTIORARI

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RULE 29.6 STATEMENT

Pursuant to Supreme Court Rule 29.6, Respondent states that it has no parent companies or non-wholly owned subsidiaries.

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Committee of Dental Amalgam Manufacturers and Distributors v. Stratton, 92 F.3d 807 (9th Cir. 1996), *cert. denied*, 519 U.S. 1084 (1997) 21

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Hawkins v. Upjohn Co., 890 F. Supp. 609 (E.D. Tex. 1994) . . . 10

Federal Cases (Cont.) **Page(s)**

Hines v. Davidowitz, 312 U.S. 52 (1941) 19, 20

Ingalls Shipbuilding, Inc. v. Director, Office of Workers' Compensation Programs, Dept. of Labor, 519 U.S. 248 (1997) 13

King v. Collagen Corp., 983 F.2d 1130 (1st Cir.), *cert. denied*, 510 U.S. 824 (1993) 14, 15

Kuiper v. American Cyanamid Co., 131 F.3d 656 (7th Cir. 1997), *cert. denied*, 118 S. Ct. 1839 (1998) 22

Lake v. U.S. Food & Drug Administration, 1989 WL 71554 (E.D. Pa. June 27, 1989) 3

Learjet Corp. v. Spenlinhauer, 901 F.2d 198 (1st Cir. 1990) . . . 10

Lewis v. Brunswick Corp., 107 F.3d 1494 (11th Cir. 1997), *cert. dism'd*, 118 S. Ct. 1793 (1998) 22

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Martin v. Telectronics Pacing Systems, Inc., 105 F.3d 1090 (6th Cir. 1997), *cert. denied*, 118 S. Ct. 850 (1998) 25

Federal Cases (Cont.) **Page(s)**

McDermott v. State of Wisconsin, 228 U.S. 115 (1913) 19

Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996) . . . . . passim

Michael v. Shiley, Inc., 46 F.3d 1316 (3d Cir.), *cert. denied*, 516 U.S. 815 (1995), *rejected by Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), *overruled by, In re Orthopedic Bone Screw Products Liability Litigation*, 159 F.3d 817 (3rd Cir. 1998) . . 14, 15, 23

Mitchell v. Collagen Corp., 67 F.3d 1268 (7th Cir. 1995), *vacated*, 518 U.S. 1030 (1996) 14, 15

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In re Orthopedic Bone Screw Products Liability Litigation, 159 F.3d 817 (3d Cir. 1998) 22

Papike v. Tambrands Inc., 107 F.3d 737 (9th Cir.), *cert. denied*, 118 S. Ct. 166 (1997) 24

Princeton University v. Schmid, 455 U.S. 100 (1982) 13, 25

Federal Cases (Cont.) **Page(s)**

Reeves v. AcroMed Corp., 44 F.3d 300 (5th Cir.), *cert. denied*, 515 U.S. 1104 (1995) 14, 15

Reeves v. AcroMed Corp., 103 F.3d 442 (5th Cir. 1997) 21

Rivers v. Roadway Express, Inc., 511 U.S. 298 (1994) 13

Seminole Tribe of Florida v. Florida, 517 U.S. 44 (1996) 13

Stanton by Brooks v. Astra Pharmaceutical Products, Inc., 718 F.2d 553 (3d Cir. 1983) 10

Symens v. SmithKline Beecham Corp., 152 F.3d 1050 (8th Cir. 1998) 21

Talbott v. C.R. Bard, Inc., 63 F.3d 25 (1st Cir. 1995), *cert. dism'd*, 517 U.S. 1230 (1996) 15

United States v. 250 Jars, etc., 344 F.2d 288 (6th Cir. 1965) 3

United States v. An Article ... Consisting of 216 Cartoned Bottles More or Less, 409 F.2d 734 (2d Cir. 1969) 3

United States v. An Article of Device...Diapulse, 768 F.2d 826 (7th Cir. 1985) 2

United States v. Rutherford, 442 U.S. 544 (1979) 4

Washington Legal Foundation v. Friedman, 13 F. Supp.2d 51, 56 (D.D.C. 1998), *order amended by* 36 F. Supp.2d 16 (D.D.C.), *amended by* 36 F. Supp.2d 418 (D.D.C. 1999) 4

Federal Cases (Cont.) **Page(s)**

Weinberger v. Hynson Westcott & Dunning, Inc., 412 U.S. 609 (1973) 4

State Cases

Armstrong v. Optical Radiation Corp., 57 Cal.Rptr.2d 763 (Cal. App. 1996) 21

Baird v. American Medical Optics, 713 A.2d 1019 (N.J. 1998) . 22

Connely v. Iolab Corp., 927 S.W.2d 848 (Mo. 1996), *cert. dism'd*, 520 U.S. 1260 (1997) 19,21,22

Dutton v. AcroMed Corp., 691 N.E.2d 738 (Ohio App. 1997) .. 22

Green v. Dolsky, 546 Pa. 400, 685 A.2d 110 (1996), *cert. denied*, 520 U.S. 1168, 1212 (1997) 16,19,21,22

Niehoff v. Surgidev Corp., 950 S.W.2d 816 (Ky. 1997), *cert. denied*, 118 S. Ct. 1187 (1998) 21

Steele v. Collagen Corp., 63 Cal. Rptr. 2d 879 (Cal. App. 1997) . 21

Walker v. Johnson & Johnson Vision Products Inc., 217 Mich. App. 705, 552 N.W.2d 679 (Mich. App. 1996) .. 21

Federal Statutes, Regulations, Rules and Legislative Materials

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Federal Statutes, Regulations, Rules and Legislative Materials (Cont.) **Page(s)**

21 U.S.C. § 321(h) 3

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Federal Statutes, Regulations, Rules and Legislative Materials (Cont.) **Page(s)**

21 U.S.C. § 365(d) 2

21 C.F.R. § 130.12 2

21 C.F.R. § 801.4 3

21 C.F.R. § 801.5 3

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Federal Statutes, Regulations, Rules and Legislative Materials (Cont.) **Page(s)**

21 C.F.R. § 890.3150 3

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1976 U.S. Code Cong. & Admin. News, 1070, 1075 2

S. Rep. No. 33, 94th Cong., 2d Sess. 2

H.R. Rep. No. 853, 94th Cong., 2d Sess. 3

BRIEF IN OPPOSITION TO PETITION FOR A WRIT OF CERTIORARI

INTRODUCTION

This Court repeatedly has articulated a policy of substantial restraint in the exercise of its review powers. *See Supreme Court Rule* 10. Plainly, this policy is not served by granting a writ of certiorari to review an appellate decision which involves the straightforward application of legal principles recently and unanimously announced by this Court. *Liles v. Oregon*, 425 U.S. 963, 964 (1976) (Stevens, J., concurring in the denial of certiorari). However, that is precisely what the instant Petition asks this Court to do.

In *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), this Court unanimously ruled that there is no preemption of state-law tort claims which are based on conduct that violates the requirements of federal medical device law. *Lohr*, 518 U.S. at 495-97 (majority opinion) & 518 U.S. at 513 (O'Connor, J., concurring in part). Applying that principle in the instant matter, the United States Court of Appeals for the Third Circuit ruled that federal law does not preempt plaintiffs' claims to recover damages under state law for the injuries which they suffered as a result of defendants' misrepresentations to the FDA. *See* Appendix of Petitioner Buckman Company to Petition for a Writ of Certiorari ("App."), 1a-25a. Since that decision represents a direct application of the principle recently and unanimously announced by this Court in *Lohr*, it should not reasonably be subject to question, let alone certiorari review. While it is true that in a prior decision the United States Court of Appeals for the Seventh Circuit held otherwise, it did so only in passing, in reliance on a pre-*Lohr* Third Circuit opinion which was overruled here, and without articulating any reasons for its holding. *See Mitchell v. Collagen Corp.*, 126 F.3d 902, 914 (7th Cir. 1997), *cert. denied*, 118 S. Ct. 1300 (1998) ("*Mitchell II*"). All of the other appellate courts that have

considered the issue have ruled, consistent with the decision of the Third Circuit here, that state-law claims predicated upon fraud on the FDA are not preempted. Therefore, any technical division of appellate authority on this issue is not sufficiently substantial or mature to warrant intervention by the Court at this time.

THE FACTS

A. The Regulatory Background

At issue in this multidistrict litigation are medical devices which are subject to regulation by the United States Food and Drug Administration ("FDA") pursuant to the Food, Drug and Cosmetic Act ("FDCA"), 21 *U.S.C.* § 301, *et. seq.*, and the Medical Device Amendments to that Act ("MDAs"), 21 *U.S.C.* § 360, *et seq.* The purpose of the FDCA and the MDAs is to protect members of the unsuspecting public from drugs and devices "which pose serious risk if inadequately tested or improperly designed or used."[1]

One of the central tenets of the legislation is that the existence and character of a drug or device is ultimately determined by the "intended use" of the article, not by its physical characteristics or

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[1] S. Rep. No. 33, 94th Cong., 2d Sess. 5, reprinted in 1976 *U.S. Code Cong. & Admin. News*, 1070, 1075. *See also, e.g.*, 21 *U.S.C.* §§ 360e(c) & 365(d); 21 *C.F.R.* §§ 814.20 & 130.12; *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475-78 (1996); *Weinberger v. Hynson Westcott & Dunning, Inc.*, 412 U.S. 609, 617-20 (1973); *United States v. An Article of Device...Diapulse*, 768 F.2d 826, 832 (7th Cir. 1985).

physiological effects.[2] Thus, for example, a screw which is intended for use in constructing a car is obviously not a medical "device" subject to any regulation by the FDA. The same screw, if intended for use in constructing crutches, would be a "Class I" medical device subject to minimal regulation. *See* 21 *C.F.R.* § 890.3150. If the same screw was intended for use in the spine, it

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[2] *See, e.g.*, 21 *U.S.C.* § 321(h) (device defined as any article "which is -- ...intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation or prevention of disease, in man or other animals...."); 21 *U.S.C.* § 321(h) ("drug" similarly defined); *Church of Scientology of California v. Richardson*, 437 F.2d 214, 216 (9th Cir. 1971); *United States v. An Article ... Consisting of 216 Cartoned Bottles More or Less*, 409 F.2d 734, 739 (2d Cir. 1969) (a cosmetic, such as shampoo, can be a drug, regardless of its actual physical effects, depending on its intended use); *United States v. 250 Jars, etc.*, 344 F.2d 288, 289 (6th Cir. 1965) (honey classified as a drug when it is sold for therapeutic purposes); H.R.Rep. No. 853, 94th Cong., 2d Sess. at 14-15 ("It is the Committees' intention that each use...be treated as constituting a different device for purposes of classification and regulation"); *Lake v. U.S. Food & Drug Administration*, 1989 WL 71554 at *5 (E.D. Pa. June 27, 1989) ("different uses pose different risks and require new proof of safety and effectiveness"); *Requests for Comments in Regard to Citizen Petition Regarding the Food and Drug Administration's Policy on Promotion of Unapproved Uses of Approved Drugs and Devices*, 59 *Fed.Reg.* 59820 (Nov. 18, 1994).

Accordingly, the intended use of a device specified by the person submitting a request to the FDA for marketing clearance delineates the scope of the FDA's review. *See* 21 *C.F.R.* §§ 801.4, 801.5, 807.87(e), 807.100(b)(1) & 814.20(b)(3)(ii).

would be a "Class III" medical device subject to extensive FDA regulation. *See* 21 *C.F.R.* § 888.3070.

Another key concept at the heart of the federal regulatory scheme arises from the legislative conviction that the safety and efficacy of drugs and devices must be demonstrated in well-controlled clinical trials and cannot be determined based on the anecdotal experience of physicians. *E.g.*, *Weinberger v. Hynson Westcott & Dunning, Inc.*, 412 U.S. 609, 619 (1973) (the "strict and demanding standards [of the FDCA], barring anecdotal evidence indicating that doctors 'believe' in the efficacy of a drug are amply justified by the legislative history [which shows] a marked concern that impressions or beliefs of physicians, no matter how fervently held, are treacherous"); *see also United States v. Rutherford*, 442 U.S. 544, 557-58 (1979) (rejecting arguments that FDA approval requirements for new intended uses could be overcome, even when terminally ill patients were to receive the treatments).[3] Accordingly, the MDAs generally provide that a medical device may not be introduced into commerce unless it

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[3] The danger of using drugs or devices based on the clinical theories or anecdotal experience of physicians rather than results of well-conducted clinical trials was vividly illustrated in the 1980's when physicians began to prescribe the drug Flecainide, off label, to treat arrhythmias in patients who recently had heart attacks. The drugs were very effective in controlling arrhythmias. However, when well-controlled trials were finally conducted with respect to this "off-label treatment," it appeared that those who took the drug had a two and one-half fold increase in mortality and that 3,000 to 10,000 patients per year had died as a consequence of this "treatment." *See Washington Legal Foundation v. Friedman*, 13 F. Supp.2d 51, 56 (D.D.C. 1998), *order amended by* 36 F. Supp.2d 16 (D.D.C.), *amended by* 36 F. Supp.2d 418 (D.D.C. 1999).

receives "premarket approval" from the FDA based on the outcome of well-controlled clinical trials and extensive FDA review.[4] *See* 21 *U.S.C.* §§ 360c(a)(1)(C) & 360e; *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996).

The principal exception to the premarket approval requirement derives from a congressional concern that manufacturers of devices which were in commerce prior to enactment of the MDAs should not receive a competitive advantage. *Lohr*, 518 U.S. at 477-79 & 493-94. This exception permits the marketing of a Class III device without premarket approval if the FDA determines that the device is "substantially equivalent" to a "predicate device." *See* 21 *U.S.C.* §§ 360(k), 360c(f) & (i); 21 *C.F.R.* § 807.100. A predicate device is one which was commercially distributed prior to May 28, 1976 or which was introduced thereafter and which was reclassified into regulatory Class I or II. *Id.* A device is "substantially equivalent" to a predicate device only if "the device has the same intended use as a predicate device." 21 *U.S.C.* § 360c(i)(1)(A); 21 *C.F.R.* § 807.100(b)(1).

Substantial equivalence, as defined by the statute, is claimed and either accepted or rejected through a premarket notification

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[4] If a manufacturer wishes to generate the scientific data necessary to obtain premarket approval, it may do so under the investigational device exemption provisions of the FDCA. 21 *U.S.C.* § 360j(g); 21 *C.F.R.* § 813, *et seq.* These provisions authorize the FDA to grant an exemption permitting experimental devices to be used without premarket approval under stringent conditions established and actively supervised by the agency. *Id.* Under FDA regulations, an investigational device may not be promoted for commercial distribution or test marketed outside of the approved IDE. *See* 21 *C.F.R.* § 812.7(a).

submitted under Section 510(k) of the Act, 21 *U.S.C.* § 360(k). By virtue of both federal statutes and FDA regulations, all statements made in connection with a premarket notification must be truthful. *See* 18 *U.S.C.* § 1001; 21 *C.F.R.* § 807.87(j). In addition, a premarket notification must include "proposed labels, labeling and advertisements sufficient to describe the device, its intended use, and the directions for its use" and "a statement indicating that the device is similar to and/or different from other products of comparable type in commercial distribution, accompanied by data to support the statement." *See* 21 *C.F.R.* § 807.87(e) & (f). If the FDA determines in response to a 510(k) notification that the device is not substantially equivalent to a lawfully-marketed predicate device, the device may not be marketed unless it receives premarket approval. Marketing of the device without premarket approval would constitute adulteration in violation of the statute. *See* 21 *U.S.C.* §§ 351(f), 352(o), 360c(a)(1)(C), 360c(f)(1) & 360e(a); 21 *C.F.R.* § 807.100(a)(2).

B. Buckman's Fraud

Petitioner, Buckman Company, is a regulatory consultant who was retained by AcroMed Corporation to assist it in obtaining marketing clearance for the Variable Screw Placement ("VSP") Spinal Plate Fixation System. App., 4a. The system was designed as an adjunct to spinal fusion surgery and consisted of plates which were to be attached to the posterior portion of the lumbar spine with screws inserted into the spinal pedicles, the bony archways which flank the spinal cord. *See* Appendix to Plaintiffs' Brief in the District Court, MDL 1014, Docket Item No. 858 (hereinafter "D.Ct.App."), Ex. # 1 at 312-14.

On September 4, 1984 and again on September 20, 1985, Buckman filed premarket notifications for the VSP device, truthfully representing that it was intended for use as a pedicle

screw fixation construct in spinal fusion surgery. App., 4a-5a. In response to each notification, the FDA expressly determined that the VSP Spinal Plate Fixation System was not substantially equivalent to any device marketed in commerce prior to May 28, 1976, and that it posed potential risks not exhibited by other spinal fixation systems including "greater chance of neurological deficit." *Id.* Therefore, the agency advised AcroMed and Buckman that the VSP system could not be commercially distributed without premarket approval. *Id.*

Determined to sell the VSP system as a pedicle screw fixation device, AcroMed and Buckman concocted an unlawful scheme to bring the VSP device components to market without premarket approval. App., 5a. Pursuant to this plan, AcroMed changed the name of the VSP device from a "spinal plate fixation system" to "nested bone plates" and "cancellous bone screws." *Id.* Then, in late December, 1985, Buckman submitted separate premarket notifications for the plates and screws in which Buckman fraudulently omitted all reference to the use of the device in the spine. App., 6a. Instead, these 510(k) notifications falsely represented to the FDA that the device components were substantially equivalent to preamendment Class II devices used to repair fractures of the arms and legs. *Id.* Consistent with this, each 510(k) notification expressly represented to the agency that there was "no new application, indication, material, device configuration or specification presented by" the device components, even though Buckman was aware that AcroMed's intention was to market the device components solely as a spinal fixation construct which the FDA had already decided was a "new application, indication and device configuration" for which 510(k) marketing clearance was not appropriate. D.Ct.App., Ex. #s 7 & 8.

Noting that the nested bone plates and cancellous bone screws were identical to the components of the VSP Spinal Plate Fixation

System which the FDA had previously refused to clear, the FDA sought clarification concerning the intended use of the plates and screws. D.Ct.App., Ex. # 1 at 92-93 & 127; Ex. # 9. On January 10, 1986, Buckman responded to this request, affirmatively representing to the FDA that: "The AcroMed plates are intended for use in appropriate fractures of long bones of both the upper and lower extremity...." App., 5a-6a (*citing* Third Circuit Appendix at A-58); D.Ct.App., Ex. # 9.

There is no question that the representations made by Buckman to the FDA concerning the intended use of AcroMed's plates and screws were fraudulent. Indeed, contemporaneous with the Buckman-AcroMed 510(k) submission to the FDA, AcroMed's President wrote a letter in which he admitted that the submission was "a labeling slight-of-hand that satisfies the agency's regulations but in no way changes the intended use of the plates and screws." D.Ct.App., Ex. # 12; Third Circuit Appendix, No. 97-1783 at A-58. In addition, in an interview with FDA enforcement officials, AcroMed's former Vice President of Operations directly admitted that "the device was always intended for use in the spine." D.Ct.App., Ex. # 14. Finally, AcroMed's President and Chief Counsel admitted, under oath, that AcroMed's plates and screws were designed solely for use in the spine. Third Circuit App. at 58; D.Ct.App., Ex. # 13 at 17.

In reliance on Buckman's misrepresentations, the FDA determined that AcroMed's nested bone plates and cancellous bone screws were substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976. App., 6a. This allowed the plate and screw components to be introduced into the marketplace without being seized by the FDA. Then, in conformity with the fraudulent scheme developed by AcroMed and Buckman, AcroMed marketed the plates and screws solely for use in the spine as a pedicle screw fixation construct. *Id.* This marketing was done

on a massive scale, largely through the promotional efforts of physicians retained by AcroMed pursuant to agreements which afforded these virtual commissioned sales agents the right to participate in the financial growth of AcroMed through very substantial stock options.[5] D.Ct.App., Ex. #s 30, 34, 35, 36 & 37. Other manufacturers adopted the Buckman-AcroMed scheme.

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[5] Such unlawful marketing resulted in FDA sanctions including withdrawal of FDA approval to conduct clinical trials regarding use of the VSP device, the issuance of numerous warning letters, and the convening of a grand jury investigation. D.Ct.App., Ex. #s 71 & 72. *See also* 63 *Fed.Reg.* at 40037-38. Notwithstanding these enforcement efforts, the marketing scheme adopted by AcroMed and other manufacturers was so successful that pedicle screw fixation gained a foothold among a segment of spine surgeons. Beginning in 1994, the FDA launched an investigation to determine whether to reclassify pedicle screw fixation devices. Despite the fact that the devices had been the subject of at least 14 different clinical trials to assess their safety and efficacy and widespread "off-label" use, the FDA concluded in 1998 that there was insufficient evidence that devices were sufficiently safe or effective to justify their reclassification for treatment of all but a handful of spinal maladies. Even for such indications, however, the agency mandated that the devices would be subject to special controls in regard to labeling, design, material composition, and biocompatibility. *See* "Orthopedic Devices: Classification & Reclassification of Pedicle Screw Spinal Systems," 63 *Fed.Reg.* 40025 (1998). Accordingly, the regulation cannot be viewed as an endorsement with regard to the safety and effectiveness of pedicle screw fixation devices generally or as a ratification of past illegal conduct which brought these devices into the hands of physicians for use in spinal surgery. *See* 63 *Fed.Reg.* at 40037-38.

C. The Proceedings Below

Many people were injured as a result of the spinal application of AcroMed's hardware for pedicle screw fixation. In the product liability litigation which resulted, some of these plaintiffs named Buckman as a defendant based on the theory that Buckman's fraud on the FDA gave rise to actionable injuries under state law.[6]

The District Court, sitting as the MDL transferee forum for all federal pedicle screw cases, dismissed these "fraud-on-the-FDA" claims under *Fed.R.Civ.P.* 12(b)(6). In doing so, it explicitly recognized that such fraud claims were not preempted, particularly in light of this Court's decision in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996). However, the District Court decided that allowing a fraud-on-the-FDA claim would essentially create a private right of action for violation of the FDCA and that, "in view of the FDA's exclusive prosecutorial discretion...any grant of an

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[6] While the issue has not been widely decided, state law appears to recognize a cause of action where a fraudulent misrepresentation induces a regulatory agency charged with the protection of the public to issue an authorization in the form of a permit, clearance, license or the like and the activity conducted pursuant to the regulatory authorization produces physical harm. *See, e.g., Learjet Corp. v. Spenlinhauer,* 901 F.2d 198, 202-03 (1st Cir. 1990) (allowing aircraft purchaser's claim against manufacturer based on misrepresentations to the Federal Aviation Administration); *Stanton by Brooks v. Astra Pharmaceutical Products, Inc.*, 718 F.2d 553, 568-69 (3d Cir. 1983) (allowing patients' claims against drug manufacturer based on misleading statements made to the FDA); *Hawkins v. Upjohn Co.*, 890 F. Supp. 609, 612 (E.D. Tex. 1994) (same).

implied private right of action would be contrary to the letter and spirit of the statute." App., 37a.

On appeal, Buckman sought to justify the District Court's opinion on its own terms and never asserted that state-law claims based on agency fraud were preempted, either expressly or impliedly. However, Sofamor Danek Group, a manufacturer of various pedicle screw fixation devices, appeared in the Court of Appeals as amicus curiae. Sofamor Danek argued that plaintiffs' fraud-on-the-FDA claims were impliedly preempted. No one argued for express preemption under 21 *U.S.C.* § 360k.

The Court of Appeals reversed, holding that no principle of federal law prevented plaintiffs from proceeding with state-law claims which were predicated upon Buckman's alleged misrepresentations to the FDA. The reasoning in support of this holding was straightforward.

First, the Court of Appeals held that "[a]bsent preemption by federal law...a district court cannot decline to enforce liability imposed by the relevant state common law." App., 14a. Second, it recognized that preemption is a matter of legislative intent and that "where Congress has expressed itself on preemption in a statute," Congress' preemptive intent is primarily "discerned from the language of the preemption statute and the 'statutory framework' surrounding it." App., 15a. Third, the Court recognized that the MDAs contain an express preemption provision, 21 *U.S.C.* § 360k, which was definitively construed by this Court in *Lohr* as manifesting a congressional intent to allow states to provide "a traditional damages remedy for violations of common law duties when those duties parallel federal requirements." App., 16a, *citing Lohr*, 518 U.S. at 495. Because plaintiffs' claims were based on a common-law duty to refrain from making misrepresentations which is identical to the duty imposed by federal

law to refrain from making misrepresentations to the FDA, the Court concluded that "the state common law relied upon does not impose any obligation on Buckman inconsistent with federal law" and accordingly was not preempted.[7] App., 13a.

REASONS TO DENY THE WRIT

A. The Question Presented by Petitioner is Not an Issue in This Case

The principal question which Buckman seeks to present to the Court by its Petition for Certiorari is "Whether a state tort claim collaterally attacking a decision of the Food and Drug Administration to permit the marketing of a medical device on the ground that the approval was obtained through a 'fraud on the agency' is expressly and impliedly preempted by the Medical Device Amendments to the Food, Drug and Cosmetic Act." This "question" has nothing whatsoever to do with this case. The plaintiffs here did not seek, and the Court of Appeals did not authorize, any "attack" on any decision by the FDA, collateral or otherwise. Rather, plaintiffs simply contended, and the Court of

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[7] The Court of Appeals also observed that:

> We do not rule out the possibility that there may be some areas of preemption outside the scope of Section 360k based on clear and direct conflicts between the requirements of state law and those of the FDCA. The existence of Section 360k, its relatively narrow scope and *Lohr*'s presumption against preemption of areas traditionally occupied by state law, however, counsel caution in finding implied preemption where no express preemption exists. App., 18a.

Appeals agreed, that there was nothing in federal law which precluded plaintiffs from seeking damages for injuries proximately caused by fraud committed on the FDA to the extent that state law would permit such recovery. Thus, the question which Buckman seeks to present for the Court's review has nothing to do with the question actually presented and decided in this case. Thus, it is non-justiciable. *Princeton University v. Schmid*, 455 U.S. 100, 103 (1982) (Supreme Court does not sit to decide hypothetical issues or to give advisory opinions); *Hall v. Beals*, 396 U.S. 45, 48 (1969) (same).

B. The Court of Appeals Decision Represents a Straightforward Application of a Recent, Unanimous Ruling by this Court

Certainly, this Court's certiorari powers are properly exercised to bring clarity to the resolution of important issues of federal law where the appellate judicial dialogue has been unable to do so. *See, e.g., Ingalls Shipbuilding, Inc. v. Director, Office of Workers' Compensation Programs Dept. of Labor*, 519 U.S. 248, 254-55 (1997); *Seminole Tribe of Florida v. Florida*, 517 U.S. 44, 45 (1996). However, where the Court has recently exercised such review powers to articulate guiding legal principles with respect to the appropriate interpretation of a federal statute, it is plainly inappropriate to invoke the re-exercise of the Court's review powers to patrol the implementation of those principles by the lower courts. *Rivers v. Roadway Express, Inc.*, 511 U.S. 298, 312-13 (1994). And, it is particularly inappropriate to do so where the decision for which certiorari review is sought involves a straightforward application of a recent, unanimous ruling by this Court. Yet, that is precisely what the instant Petitioner asks of this Court.

The MDAs include an express preemption provision, 21 *U.S.C.* § 360k. Section 360k states:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement -- (1) which is different from, or in addition to, any requirement applicable under this chapter to the device....

Before this Court's decision in *Lohr*, most of the Courts of Appeals held that the available FDA marketing clearances or approvals (*i.e.*, investigational device exemptions, 510k clearances and premarket approvals) as well as general FDA labeling and manufacturing regulations, constituted preempting "federal requirements" under Section 360k which totally displaced the availability of common-law tort remedies which were construed as preempted "state-law requirements."[8] As a necessary consequence of this view, they ruled that under section 360k, "states have no authority to police [a manufacturer's] compliance with the FDA's

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[8] *E.g., Mitchell v. Collagen Corp.*, 67 F.3d 1268 (7th Cir. 1995), *vacated*, 518 U.S. 1030 (1996); *English v. Mentor Corp.*, 67 F.3d 477 (3d Cir. 1995), *vacated*, 518 U.S. 1030 (1996); *Lohr v. Medtronic, Inc.*, 56 F.3d 1335 (11th Cir. 1995), *aff'd in part, rev'd in part*, 518 U.S. 470 (1996); *Michael v. Shiley Inc.*, 46 F.3d 1316 (3d Cir.), *cert. denied*, 516 U.S. 815 (1995), *rejected by Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), *overruled by In re Orthopedic Bone Screw Products Liability Litigation*, 159 F.3d 817 (3rd Cir. 1998); *Reeves v. AcroMed Corp.*, 44 F.3d 300 (5th Cir.), *cert. denied*, 515 U.S. 1104 (1995); *Gile v. Optical Radiation Corp.*, 22 F.3d 540 (3d Cir.), *cert. denied*, 513 U.S. 965 (1994); *King v. Collagen Corp.*, 983 F.2d 1130 (1st Cir.), *cert. denied*, 510 U.S. 824 (1993).

procedures." *E.g., Michael*, 46 F.3d at 1329.[9] This view was buttressed by the observation that the FDCA did not expressly or impliedly afford a private damage."[10] Thus, these courts ruled that state-law claims based on violations of FDA regulations, including fraud on the FDA, were preempted by Section 360k.[11]

The decision of this Court in *Lohr* completely rejected both the rulings and the underlying reasoning of this body of federal appellate law. *Lohr* involved claims of preemption with respect to a medical device which, like the devices at issue here, had been cleared for commercial distribution pursuant to the 510k premarket notification process. *Lohr*, 518 U.S. at 470. Although the Petitioner characterizes *Lohr* as a "fractured four-one-four" opinion, the decision of the Court was unanimous in two important respects.

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[9] *See also Talbott v. C.R. Bard, Inc.*, 63 F.3d 25, 28-29 (1st Cir. 1995), *cert. dism'd*, 517 U.S. 1230 (1996); *English*, 67 F.3d at 482-83; *Mitchell I*, 67 F.3d at 1283; *Lohr*, 56 F.3d at 1343; *Reeves*, 44 F.3d at 306; *Gile*, 22 F.3d at 544; *King*, 983 F.2d at 1140.

[10] *Lohr*, 56 F.3d at 1343; *Michael*, 46 F.3d at 1329; *Reeves*, 44 F.3d at 307; *National Bank of Commerce of El Dorado v. Kimberly-Clark Corp.*, 38 F.3d 988, 992 n.2 (8th Cir. 1994); *Gile*, 22 F.3d at 544; *King*, 983 F.2d at 1140.

[11] *Mitchell I*, 67 F.3d at 1283; *Talbot*, 63 F.3d at 28-29; *Lohr*, 56 F.3d at 1343; *Michael*, 46 F.3d at 1329; *Reeves*, 44 F.3d at 306; *Gile*, 22 F.3d at 544. Contrary to Petitioner's assertion, all of these cases were based on express preemption under Section 360k, not on any principle of implied preemption.

First, all of the members of the Court agreed that while the FDA is required to examine 510k notifications with a concern for safety and effectiveness, nothing in the statute requires it to make a determination that the device at issue is safe or effective. *Lohr*, 518 U.S. at 493-94 (majority) & 513 (O'Connor, J., concurring in part). Therefore, all of the members of the Court agreed that a 510k clearance determination by the FDA does not represent a "requirement" sufficient to displace state law. *Id.*

The consequences of this aspect of *Lohr* for the present case are clear. Just as there is nothing in the statute or regulations regarding the 510k notification process which requires the FDA to come to a specific conclusion regarding device safety in terms of the design, labeling or manufacture of devices, there is nothing in the statute or regulations which requires the agency to evaluate the truthfulness of a 510k submission with respect to intended use or any other matter. *See* 21 *U.S.C.* §§ 360c(f)(1), 360c(i)(1)(A); 21 *C.F.R.* § 807.100. Thus, while the FDA may consider questions of truthfulness just as it may consider questions of design safety or labeling adequacy in evaluating a 510k notification, it is not compelled to do so. Therefore, an FDA clearance determination no more represents a preempting "requirement" with respect to the representations made in connection with a 510k notification than it represents a preempting requirement with regard to the design or labeling of a device under *Lohr*, and a liability determination based on such representations under state law would no more represent an impermissible "collateral attack" on the FDA's 510k determination than it did in *Lohr*.[12]

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[12] *See, e.g., Green v. Dolsky*, 546 Pa. 400, 685 A.2d 110, 118-19 (1996) (holding that while premarket approval is a specific requirement which determines adequacy of device design and labeling and therefore preempts state-law design and labeling (continued...)

The second area of unanimity in *Lohr* which is significant here was the Court's treatment of the issue of whether Section 360k preempts state-law claims based on conduct which violates the requirements of Federal Medical Device Law. With respect to this issue, the Court explicitly recognized that there is no private right to relief for violations of the FDCA. *Lohr*, 518 U.S. at 487. Notwithstanding this, it unanimously rejected the rationale of those cases which held that Section 360k deprived the states of any authority to "police a defendant's compliance" with FDA regulations. Rather, the Court found that because the MDAs preempt only state-law requirements which are "different from or in addition to" federal requirements and because allowing a remedy for unlawful conduct does not amount to the imposition of a "requirement," the MDAs, by their express terms, do not preempt state-law claims to the extent that they seek damages for alleged violations of federal requirements. *Lohr*, 518 U.S. at 495-97 (majority opinion) and 518 U.S. at 513 (O'Connor, J., concurring in part).[13] In fact, the Court observed, the statutory language of

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[12] (...continued)
claims, premarket approval does not adjudicate the truthfulness of the information supplied to the FDA and, therefore, does not preempt claims that the manufacturer provided the FDA with false, fraudulent or incomplete information), *cert. denied*, 520 U.S. 1168, 1212 (1997).

[13] In this regard, Justice O'Connor's Opinion states:

> I also agree that the Lohrs' claims are not preempted by § 360k to the extent that they seek damages for Medtronics' alleged violation of federal requirements. Where a state cause of action seeks to enforce an FDCA requirement, that claim does not impose a requirement that is (continued...)

Section 360k may manifest an intent to foster state-law claims for violations of FDCA requirements in order to "provide[ ] another reason for manufacturers to comply with ... existing 'requirements' under federal law." *Id.* at 495. *See also id.* at 513 (O'Connor, J., concurring in part) ("to be sure, the threat of a damages remedy will give manufacturers an additional cause to comply [with federal requirements]").

This unanimous ruling literally compelled the conclusion reached by the Court of Appeals here. Federal statutory law expressly prohibits the making of fraudulent statements and representations to federal agencies. *See* 18 *U.S.C.* § 1001. Moreover, FDA regulations expressly require that premarket notifications submitted pursuant to Section 510k contain truthful information. *See* 21 *C.F.R.* § 807.87(j). The basis for plaintiffs' fraud claim is that Buckman and others defrauded the FDA by making false statements to the agency concerning an issue of paramount regulatory concern -- the intended use of AcroMed orthopedic plates and screws. Thus, plaintiffs seek recovery for conduct which violates federal law. If *Lohr* was clear about anything, it was clear that such claims are not preempted. Thus, the decision of the Court of Appeals here reflected a conclusion

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[13] (...continued)

> "different from, or in addition to" requirements under federal law. To be sure, the threat of a damages remedy will give manufacturers an additional cause to comply, but the requirements imposed on them under state and federal law do not differ. Section 360k does not preclude states from imposing different or additional *remedies*, but only different or additional *requirements*.

518 U.S. at 513.

which inevitably followed from recent, unanimous precedent by this Court for which certiorari review is particularly inappropriate.

Perhaps sensing this weakness in its position, Petitioner invokes the principle of implied preemption to attract the Court's attention to the issue of whether plaintiffs may bring a state-law claim for injuries caused by fraud on the FDA. However, the principles of implied preemption are just as clear as the rules of express preemption and equally unavailing to Petitioner here.

Implied preemption is a well-defined, narrowly-construed doctrine that provides for preemption in only two specific, discrete circumstances.

The first circumstance requires a demonstration that it would be impossible to comply with both state and federal law at the same time. *See, e.g., Lohr*, 518 U.S. at 507 (Breyer, J., concurring); *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995); *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963); *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941). A good example of a case warranting this type of implied conflict preemption is where state law would impose liability on a manufacturer for using a label required by federal law. *See, e.g., McDermott v. State of Wisconsin*, 228 U.S. 115, 133-34 (1913); *Moore v. Kimberly-Clark Corp.*, 867 F.2d 243, 245-47 (5th Cir. 1989). Plainly, federal law does not permit or require fraudulent statements or prohibit truthful disclosure of information such that state common-law fraud claims would come into actual conflict with specific federal regulatory requirements. *See Connely v. Iolab Corp.*, 927 S.W.2d 848, 853-55 (Mo. 1996), *cert. dism'd*, 520 U.S. 1260 (1997); *Green*, 685 A.2d at 118. Under such circumstances, the assertion of implied "conflict" preemption would be specious.

For the same reason, Petitioner cannot demonstrate the second circumstance which warrants implied preemption -- that "state-law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *See, e.g., Lohr*, 518 U.S. at 507 (Breyer, J., concurring); *Freightliner*, 514 U.S. at 287-88; *Florida Lime*, 373 U.S. at 142-43; *Hines v. Davidowitz*, 312 U.S. at 67. As *Lohr* observed, permitting state-law claims for conduct in violation of federal requirements, such as perpetrating a fraud on the FDA, serves to secure compliance with federal law. *See Lohr*, 518 U.S. at 495 (majority) & 518 U.S. at 513 (O'Connor, J., concurring in part). Thus, permitting a state-law claim for fraud on the FDA serves the objectives of federal law. It does not stand as an obstacle to the accomplishment of those objectives. This conclusion is all the more compelling considering that Congress expressly considered the extent to which FDA actions should displace state law in Section 360k and made an express determination not to preempt state-law claims of the type presented here. *See, e.g., Freightliner Corp. v. Myrick*, 514 U.S. 280, 288 (1995); *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 517 (1992). Accordingly, this type of implied preemption is also unavailable here.

For all of these reasons, it is clear that the Court of Appeals decision in the present case represents a straightforward application of clear principles of law which have been firmly established by this Court and does not engender the kind of legal uncertainty which requires resolution by the exercise of this Court's certiorari powers.

C. There is No Substantial Appellate Conflict Concerning Whether "Fraud-on-the-FDA" Claims are Preempted

Every appellate court which has considered the issue after *Lohr* has ruled that state-law claims based on a violation of the MDAs are not preempted as "collaterally attacking" or otherwise usurping the FDA's function.[14] Consistent with this, virtually every appellate court which has considered the question after *Lohr* has ruled that state-law claims arising from fraud on the FDA are not

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[14] *See, e.g., Goodlin v. Medtronic, Inc.*, 167 F.3d 1367, 1381-82 (11th Cir. 1999); *Martin v. American Medical Systems, Inc.*, 116 F.3d 102, 104 (4th Cir. 1997); *Duvall v. Bristol-Myers-Squibb Co.*, 103 F.3d 324, 330 (4th Cir. 1996); *Reeves v. AcroMed Corp.*, 103 F.3d 442, 447 (5th Cir. 1997); *Chambers v. Osteonics Corp.*, 109 F.3d 1243, 1248-49 (7th Cir. 1997); *Symens v. SmithKline Beecham Corp.*, 152 F.3d 1050, 1055 (8th Cir. 1998); *Committee of Dental Amalgam Manufacturers and Distributors v. Stratton*, 92 F.3d 807, 812-13 (9th Cir. 1996), *cert. denied*, 519 U.S. 1084 (1997); *Oja v. Howmedica, Inc.*, 111 F.3d 782, 789 (10th Cir. 1977); *Niehoff v. Surgidev Corp.*, 950 S.W.2d 816, 822 (Ky. 1997), *cert. denied*, 118 S. Ct. 1187 (1998); *Green v. Dolsky*, 546 Pa. 400, 685 A.2d 110 (1996), *cert. denied*, 520 U.S. 1168 (1997); *Armstrong v. Optical Radiation Corp.*, 57 Cal.Rptr.2d 763. 768, 772 (Cal. App. 1996); *Connelly v. Iolab Corp.*, 927 S.W.2d 848 (Mo. 1996), *cert. dism'd*, 520 U.S. 1260 (1997); *Walker v. Johnson & Johnson Vision Products Inc.*, 217 Mich.App. 705, 719, 552 N.W.2d 679, 686 (Mich.App. 1996); *Steele v. Collagen Corp.*, 63 Cal.Rptr.2d 879 (Cal.App. 1997).

preempted.[15] Thus, the status quo does not present the kind of judicial conflict which suggests a need for certiorari review. Nevertheless, Buckman posits that there is a serious division in the Courts of Appeals over whether fraud-on-the-FDA claims are undone by federal law. Plainly, this is not the case.

The sources which Buckman uses in an attempt to generate the appearance that there is a serious judicial debate warranting a unifying resolution by this Court simply don't bear the weight of that effort. *Kuiper v. American Cyanamid Co.*, 131 F.3d 656 (7th Cir. 1997), *cert. denied*, 118 S. Ct. 1839 (1998), was a case involving express preemption under FIFRA. It did not involve any claim of fraud on any agency and is so obviously unrelated to the issues here that it was not cited by Buckman in any of the proceedings in the Court of Appeals. *Lewis v. Brunswick Corp.*, 107 F.3d 1494 (11th Cir. 1997), *cert. dism'd*, 118 S. Ct. 1793 (1998), involved the Coast Guard's enforcement of the Federal Boat Safety Act and is so unrelated to the issues raised here that neither Buckman nor its amici cited the case in their briefs or at oral argument in the Court of Appeals. Moreover, to the extent that *Lewis* found that damage claims arising from fraud on the Coast Guard were preempted, it did so without citation to or discussion of a single legal authority. *See Lewis*, 107 F.3d at 1505. Similarly, while the Seventh Circuit ruled in *Mitchell II* that fraud-on-the-FDA claims were preempted, it did so only in passing, without expressing any legal reasons for this conclusion and

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[15] *See, e.g., In re Orthopedic Bone Screw Products Liability Litigation*, 159 F.3d 817 (3d Cir. 1998); *Green v. Dolsky*, 546 Pa. 400, 685 A.2d 110,117-18 (1996); *Connelly v. Iolab Corp.*, 927 S.W.2d 848, 855 (Mo. 1996); *Dutton v. AcroMed Corp.*, 691 N.E.2d 738, 811-12 (Ohio App. 1997); *Baird v. American Medical Optics*, 713 A.2d 1019, 1030 (N.J. 1998).

without citing any authority to support it other than a pre-*Lohr* decision by the Third Circuit which was subsequently found by that Court to have been overruled in *Lohr*.[16] *See Mitchell v. Collagen Corp.*, 126 F.3d 902, 914 (7th Cir. 1997), *cert. denied*, 118 S. Ct. 1300 (1998). Finally, although Judge Cowen's dissent in this case discusses policy considerations which might be raised in a legislative debate concerning preemption, nothing in his dissenting opinion discusses the applicable legal standards for determining whether Congress has, in fact, manifested a legislative intent to preempt state-law claims or attempts to explain why such standards would require preemption in the circumstances presented here. App., 25a-32a.

Thus, Buckman has failed to point to any source which indicates that there is a genuine, reasoned, legal debate concerning the matters at issue here which exists at the appellate level, let alone one that has matured to the point that Supreme Court intervention is appropriate.

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[16] In reaching its conclusion, the Court in *Mitchell II* relied on the Third Circuit's pre-*Lohr* ruling in *Michael v. Shiley*, 46 F.3d 1316 (3d Cir. 1995). In the instant case, one of the authors of the Third Circuit's *Michael* Opinion found that it had been overruled by *Lohr*. App., 16a-17a. Given this, the Seventh Circuit may well recede from its perfunctory ruling that fraud-on-the-FDA claims are preempted if it is given the opportunity to do so. Further, *Mitchell II* involved preemption with respect to a device which reached the market through premarket approval and not through 510k clearance. While the preemptive implications of premarket approval may be ambiguous, *Lohr* clearly established that an FDA decision to issue a 510k clearance is not preemptive. Consequently, *Mitchell II* is distinguishable on this basis.

D. This Case Does Not Present An Appropriate Vehicle to Resolve Any Conflict Regarding the Issue of Whether an FDA Marketing Approval Can Preempt State Laws of General Applicability

It is true that the Court in *Lohr* did not resolve by a clear majority the question of whether there can ever be preemption of state tort laws of general applicability under Section 360k. 518 U.S. at 504-05 & 509 (Breyer, J., concurring in part). Moreover, while the Court in *Lohr* held that a 510k clearance will not be preemptive, it did not by a clear majority express any principle sufficient to resolve the question of whether other FDA device marketing "approvals" -- specifically, an investigational device exemption or a premarket approval[17] -- qualify as preempting federal "requirements" for purposes of Section 360k. *Id.* In practical terms, this has left open the question of whether an FDA decision to grant a premarket approval or an investigational device exemption preempts product liability claims relating to the devices which are subject to such approvals. And the Courts of Appeals are, to some extent, divided as to the resolution of that question.[18]

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[17] Under the statute, the FDA may not grant premarket approval unless it finds that there is "reasonable assurance that [the] device is safe under the conditions of use prescribed, recommended or suggested in the proposed labeling thereof." *See* 21 *U.S.C.* § 360e(d)(2). Similarly, an IDE will only be granted where the applicant satisfies a number of express statutory conditions relating to the safety of the proposed experimental device use. *See* 21 *U.S.C.* § 360j(g); 21 C.F.R. § 813, *et seq.*

[18] *Compare, e.g., Oja v. Howmedica*, 111 F.3d 782, 789 (10th Cir. 1997) (no preemption) *with Papike v. Tambrands Inc.*, 107 F.3d 737, 742 (9th Cir.), *cert. denied*, 118 S. Ct. 166 (1997) (continued...)

It is not clear that this division has reached the point that Supreme Court intervention is required to clarify the law. However, if the issue is to be decided by the Court, it should not be resolved as an abstract proposition of law but as part of a controversy in which its resolution will actually make a difference to the outcome. *Princeton University v. Schmid*, 455 U.S. 100, 103 (1982); *Hall v. Beals*, 396 U.S. 45, 48 (1969). This is not such a case.

First, this case does not present the real question engendered by the cited intercircuit split -- whether an IDE or PMA can be preemptive -- because this case only involves a 510k clearance. Second, even if this Court were to conclude that generally applicable tort law could be preempted by some federal requirements under the MDAs, there would still be no preemption of plaintiffs' claims against Buckman. This is because those claims are based on a violation of federal law and because this Court unanimously held in *Lohr* that such claims are not preempted.

Thus, this case does not present a proper vehicle to resolve the broad question of whether state laws of general applicability can be preempted by an FDA requirement or the relevant subsidiary question of whether an FDA decision to grant a premarket approval or investigational device exemption is preemptive of state tort claims arising from the use of a device which is subject to such an exemption or approval.

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[18] (...continued)
(preemption) ; *Martin v. Telectronics Pacing Systems, Inc.*, 105 F.3d 1090, 1099 (6th Cir. 1997), *cert. denied*, 118 S. Ct. 850 (1998) (same); *Duvall v. Bristol-Myers-Squibb Co.*, 103 F.3d 324, 330 (4th Cir. 1996) (same).

CONCLUSION

For the foregoing reasons, Respondent respectfully submits that the Petition for Certiorari should be denied.

Respectfully submitted.

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In the Supreme Court of the United States

THE BUCKMAN COMPANY,

Petitioner,

v.

'PLAINTIFFS' LEGAL COMMITTEE,

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Third Circuit

REPLY BRIEF FOR PETITIONER

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REPLY BRIEF FOR PETITIONER

In their brief in opposition, plaintiffs either concede outright or make no serious effort to dispute all of the essential reasons why review should be granted: there are sharp divisions among the circuits on both questions presented; the issues raised are recurring and of immense practical significance; and the conflicts in the lower courts stem from ambiguities in this Court's decision in *Medtronic Inc.* v. *Lohr*, 518 U.S. 470 (1996), which the lower courts are incapable of resolving. Although plaintiffs attempt to defeat review by insisting that this case is nonjusticiable or a poor vehicle, or by nibbling away at the edges of our submissions, their arguments are unconvincing. Further review is plainly warranted.

1. *The Issues Presented Are Important And Recurring.* Plaintiffs do not (and could not) dispute that the petition presents issues of enormous practical importance. See Pet. 16-19, 25 (explaining impact of decision below on thousands of cases involved in this multidistrict litigation, on the availability of the preemption defense under a wide range of statutes, and on the medical device industry and the public health).

The broad significance of the "fraud on the agency" issue is strongly confirmed by all three national organizations that have filed *amicus* briefs urging this Court to grant review. See Br. of Product Liability Advisory Council, Inc. ("PLAC Br.") 5, 9-13 (discussing adverse effect on federal policies and purposes, on regulatory processes, and on agency resources); Br. of Medical Device Manufacturers' Ass'n ("MDMA Br.") 2-14 (discussing likely disruption of agency processes and personnel, delay in approval of new therapies, inhibition on flow of information concerning beneficial off-label uses, and negative impact on manufacturer incentives); Br. of Pharmaceutical Research and Manufacturers' Ass'n ("PhRMA Br.") 2-3, 6, 18-19 (describing adverse effect on availability of new medications, on research into off-label

uses, and on public health). Moreover, the question whether federal law preempts "fraud on the agency" claims has arisen not only under the MDA but also under a host of other federal statutes. Pet. 10-12, 15-16 & nn.5-6; PLAC Br. 4-5.

The second issue presented — whether the MDA preempts state requirements that are imposed through tort laws of general applicability — is also important because it arises with great regularity in tort actions involving medical devices. Indeed, as plaintiffs themselves take pains to point out (Br. in Opp. 24-25), this issue is not limited to cases involving medical devices cleared through the 510(k) process. It also frequently arises in cases involving investigational and premarket-approved devices. In addition, the issue (and the precise meaning of the Court's treatment of it in *Medtronic*) has arisen in cases involving other statutory preemption provisions. Pet. 23 & n.12. The importance of the second question presented thus extends beyond the MDA.

2. *This Case Is A Good Vehicle For Resolving The Intercircuit Conflicts On Both Issues Presented.* Plaintiffs admit that, in conflict with the Third Circuit's decision in this case, "the Seventh Circuit ruled in *Mitchell II* that fraud-on-the-FDA claims were preempted." Br. in Opp. 22. They also acknowledge that, as we demonstrated in the petition (at 10-11, 22-23 & nn. 11-13), the lower courts are "divided" over the second question presented. Br. in Opp. 24 & n.18. And they make no effort to dispute our showing (Pet. 20 n.9) of substantial conflicts in the circuits, since *Medtronic*, over the underlying question whether *Chevron* deference is owed to an agency's interpretation of an express preemption clause.

Unable to deny the existence of these conflicts, plaintiffs fall back on a hodgepodge of arguments aimed at diminishing the extent or importance of the lower courts' confusion or persuading the Court that this case is a poor vehicle to resolve the issues presented. These efforts are unavailing.

a. Plaintiffs suggest that the conflict with the Seventh Circuit on whether the MDA preempts "fraud on the agency" claims is insubstantial because the Seventh Circuit's holding was "perfunctory" and rendered "only in passing, without expressing any legal reasons for this conclusion and without citing any authority to support it other than a pre-[*Medtronic*] decision by the Third Circuit which was subsequently found by that Court to have been overruled in [*Medtronic*]." Br. in Opp. 22-23 & n.16; see also *id.* at 1. This argument is flawed at every turn.

In holding that "fraud on the agency" claims are preempted, the Seventh Circuit declared:

> **We do not believe that our earlier decision that this ["fraud on the agency"] claim is preempted is altered by *Medtronic*.** We continue to believe that this issue was decided correctly by the Third Circuit in *Michael v. Shiley, Inc.*

Mitchell v. *Collagen Corp.*, 126 F.3d 912, 914 (7th Cir. 1997) (citation omitted; emphasis added), cert. denied, 118 S. Ct. 1300 (1998). Far from being a statement made only "in passing," the highlighted sentence is a direct and emphatic rejection of the rationale adopted by the Third Circuit in this case. Moreover, contrary to plaintiffs' contention, the Seventh Circuit expressly relied on its "earlier decision" in *Mitchell I* and not just on the Third Circuit's decision in *Michael*. As plaintiffs neglect to mention, *Mitchell I* contained an extended analysis of why "fraud on the FDA" claims are preempted (see *Mitchell* v. *Collagen Corp.*, 67 F.3d 1268, 1283 (7th Cir. 1995), vacated, 518 U.S. 1030 (1996)) — an analysis that relied not just on *Michael* but also on several First and Fifth Circuit decisions reaching the same conclusion. There was simply no reason for the Seventh Circuit to rehash all of this in rejecting the only new point before it: whether *Medtronic* had affected the analysis in

Mitchell I.[1]

In any event, it cannot be seriously disputed that district courts in the Seventh Circuit are bound to follow the holding of *Mitchell II*. Those courts are not at liberty to allow "fraud on the agency" claims to proceed, nor could they credit the argument (on which the decision below in this case rests) that *Medtronic* alters pre-*Medtronic* law on this score.[2]

b. In an effort to minimize the conflict on the first issue presented, plaintiffs assert that, with the exception of *Mitchell II*, "[a]ll of the other appellate courts that have considered the issue" of whether "fraud on the FDA" claims are preempted "have ruled, consistent with the Third Circuit here," that such claims are not preempted. Br. in Opp. 1-2. That assertion blithely ignores the substantial case law decided before *Medtronic*, which we identified in the petition (at 11-12 & n.5), and which remains in effect unless it was altered by *Medtronic* (an issue over which the lower courts have sharply disagreed). It also overlooks numerous pre- and post-*Medtronic* decisions involving preemption provisions that are analogous to 21 U.S.C. § 360k(a). See *id.* at 11 & n.5, 15-16; see also PLAC Br. 4-5.

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[1] Plaintiffs wishfully suggest that the Seventh Circuit "may well recede from its perfunctory ruling that 'fraud on the agency' claims are preempted if given an opportunity to do so." Br. in Opp. 23 n.16. Plaintiffs mistake for perfunctoriness the Seventh Circuit's emphatic rejection of an argument it regarded as meritless.

[2] Plaintiffs also suggest that *Mitchell* is "distinguishable" because it involved a device that "reached the market through premarket approval and not through the 510k clearance." Br. in Opp. 23 n.16. But a "fraud on the agency" claim is just as much of a collateral attack on the FDA's clearance decisions, whether those decisions are made in the 510(k) process or in the premarket approval process. See note 3, *infra*.

c. Plaintiffs devote several pages to arguing that the "fraud on the agency" question as stated in our petition "has nothing whatsoever to do with this case" and, accordingly, this case is "non-justiciable." Br. in Opp. 12-13. That is so, plaintiffs contend, because a "fraud on the agency" claim in no way "attacks" an FDA decision. *Ibid*. This argument boils down to a quibble with the phrasing of one of our questions presented.[3] Such a disagreement hardly renders the "fraud on the agency" issue non-justiciable. And since plaintiffs have failed to rephrase the first question presented in their opposing brief, any objection they might have to the question as phrased in our petition has been waived. S. Ct. Rule 15.2.

Plaintiffs also assert that we never argued below "that state-law claims based on agency fraud were preempted, either expressly or impliedly." Br. in Opp. 11. They are wrong again. We raised and argued both express and implied preemption below. See Pet. C.A. Br. 9-12 & n.5; Pet. for Reh'g 4-11.[4]

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[3] Our phrasing is entirely correct. Plaintiffs seek to have a jury impose penalties based on the FDA's decision to give marketing clearance to the bone screws at issue, which the FDA has continued explicitly to sustain. See Pet. 6, 17 n.7. It is difficult to see how this claim can be characterized as anything other than an "attack" on the FDA's decisions. See *Lewis* v. *Brunswick*, 107 F.3d 1494, 1505 (11th Cir. 1997) ("indirect[]" "challenge[]"), cert. dismissed, 118 S. Ct. 1793 (1998); see also *Reeves* v. *AcroMed Corp.*, 44 F.3d 300, 307 (5th Cir.) ("collateral attack"), cert. denied, 515 U.S. 1104 (1995).

[4] Moreover, defendants Sofamor, S.N.C. and Danek Medical, Inc. submitted to the Third Circuit a joint brief as appellees, which set forth an extended argument for implied and express preemption. C.A. Br. of Appellees Sofamor & Danek 13-28; Pet. App. 8a n.3. The court determined that they lacked standing to appeal, but treated their submission as an *amicus* brief. Pet. App. 8a n.3.

Not surprisingly, plaintiffs do not contend that the express and implied preemption arguments advanced in the petition have been waived. That argument would be meritless, since under this Court's cases an issue is preserved for review if it was either *raised or decided* by the court below. See *United States* v. *Williams*, 504 U.S. 36, 40 (1992). There is no dispute that the Third Circuit rejected both implied and express preemption theories. Pet. 8-9. The "fraud on the agency" issue thus was both raised *and* decided below.

d. On the second question presented, we documented the existence of a 4-2 circuit split on whether the MDA can preempt state tort requirements of general applicability. Pet. 22-23 & nn. 11-12; see also MDMA Br. 15. Another three circuits, we explained, have endorsed the majority view by holding that tort requirements of general applicability are preempted by statutes analogous to the MDA. Pet. 23. And eight state appellate courts (including the Supreme Courts of Oregon, Pennsylvania, and Kentucky) have reached conclusions that are contrary to the federal circuits in which they are located. *Id.* at 24 & n.14. Multiple state and federal trial courts have reached conflicting results as well. *Id.* at 23 & n.13.

In response to this showing of disarray, plaintiffs say that "this division has not reached the point that Supreme Court intervention is required to clarify the law." Br. in Opp. 25. But plaintiffs provide no good reason why this Court should tolerate these serious and far-reaching conflicts until the Second, Fifth and Eleventh Circuits have addressed the issue. At most, if those circuits all side with the Third and Tenth Circuits, the position advocated by plaintiffs will still represent only a minority view in the federal courts of appeals. Moreover, the lower courts' confusion on this issue is traceable, in the end, to ambiguities in this Court's decision in *Medtronic*. See Pet. 20-23. Those ambiguities can be resolved by this Court alone, and they are not likely to be

further illuminated by waiting for the Second, Fifth and Eleventh Circuit to take sides in the debate.

In sum, the disagreements in the lower courts are substantial and recurring and plainly warrant this Court's intervention. As the Solicitor General recommended more than a year ago when the confusion was less extensive, this Court should "grant review and definitively resolve the conflict" in an appropriate case. No. 96-1405 U.S. Br. 18, *Smiths Indus. Med. Sys.* v. *Kernats*. This is that case.

Plaintiffs next argue that "this case does not present the real question engendered by the cited intercircuit conflict" because "this case only involves a 510k clearance." Br. in Opp. 25. Plaintiffs conflate two issues: (1) Which *federal* requirements trigger express preemption under the MDA? and (2) Which *state* requirements can be preempted by that statute? The conflict we identify in the petition is a conflict on how the second issue should be resolved. It is true (but completely irrelevant) that the lower courts have *also reached conflicting conclusions* about how the *first* issue should be resolved in light of *Medtronic*. Specifically, as plaintiffs note, the lower courts have disagreed over "whether an IDE or PMA can be preemptive." Br. in Opp. 25. That conflict, however, is not presented in this case — and we have never suggested otherwise.

Relatedly, plaintiffs maintain that this case is a poor vehicle for resolving the second question presented because even if the Third Circuit was wrong and state tort requirements of general applicability can be preempted, "there would still be no preemption of plaintiffs' claims against Buckman" because "fraud on the agency" claims are never preempted. Br. in Opp. 25. In essence, this amounts to an argument that the Court would not need to resolve the second question presented if it ruled in plaintiffs' favor on the first question. That argument puts the cart before the horse.

Even if plaintiffs are right that this Court is required to

address the two questions in a particular order, which is doubtful,[5] that would hardly make this case a poor vehicle. This Court frequently grants review in cases raising several issues, where a ruling on one issue may obviate the need to resolve the other question or questions presented. See, *e.g.*, *American Mfrs. Mut. Ins. Co.* v. *Sullivan*, 119 S. Ct. 977 (1999); *Heck* v. *Humphrey*, 512 U.S. 477 (1994). In addition, this Court is not prohibited from deciding both issues in such cases, when there is good reason to do so. *E.g.*, *Sullivan*, 119 S. Ct. at 989 (deciding due process issue even "[t]hough our resolution of the state action issue would be sufficient by itself to reverse the judgment of the Court of Appeals").

3. *The Decision Below Is Erroneous.* a. Plaintiffs devote most of their brief to arguments on the merits. They maintain that the Third Circuit's refusal to find the "fraud on the agency" claim preempted was a "straightforward application of a recent, unanimous ruling by this Court." Br. in Opp. 13; see also *id.* at 1, 13-20. In plaintiffs' view, if *Medtronic* "was clear about anything, it was clear that" claims of "fraud on the agency" are not preempted by the MDA. Br. in Opp. 18. Plaintiffs even go so far as to say that *Medtronic* "literally compelled the conclusion reached by the Court of Appeals here." *Ibid.*

All of this, of course, would come as news to the three-judge panel of the Seventh Circuit in *Mitchell II*, which unanimously and emphatically declared: "We do not believe that our earlier decision that this ["fraud on the agency"] claim is preempted is altered by *Medtronic*." 126 F.3d at

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[5] The Court might reasonably conclude that the second question identified in the petition is logically prior to the first question presented, because it concerns the threshold issue of whether *any* state law tort claims are preempted, as opposed to preemption of just "fraud on the agency" claims.

914. It would also come as news to Judge Cowen, who dissented from the panel's decision. And we suspect that it would come as news to the various circuits that have ruled, since *Medtronic*, that "fraud on the agency" claims are preempted under analogous federal preemption schemes. See Pet. 10-11, 15.

Beyond that, plaintiffs' contention that *Medtronic* compels the result below is inherently implausible because *Medtronic* did not involve any "fraud on the agency" claim. As we explained in the petition (at 25-29), "fraud on the agency" claims are fundamentally different from the design defect claim held not to be preempted in *Medtronic*. See also PLAC Br. 16-18; Br. of Danek Medical, Inc. ("Danek Br.") 10-13. A "fraud on the FDA" claim directly attacks the agency's clearance decision; it requires a lay jury to guess as to what the FDA would have done in the absence of the "fraud"; it focuses not on representations made to physicians or patients but on the accuracy of submissions made to the federal agency; it is dependent (in ways ordinary product liability claims are not) on the very existence of the federal regulatory scheme; and it threatens to interject state courts into the internal decisionmaking processes of federal agencies and sap agency resources. Plaintiffs do not deny these differences.

Moreover, as we explained in the petition (at 27-29), *Medtronic* did not decide any issue of *implied* preemption. The Court's analysis focused instead on the question of *express* preemption. Accordingly, *Medtronic* could not possibly have "compelled" (Br. in Opp. 18) the panel majority's conclusion that "fraud on the agency" claims are not impliedly preempted by federal law.

b. We explained in the petition (at 26-27) that plaintiffs' "fraud on the agency" claim is expressly preempted by the MDA because it imposes "different" requirements than are applicable under federal law to the pedicle screws at issue in this case. 21 U.S.C. § 360k(a). Specifically, plaintiffs' state

law claims would threaten to impose liability for failing to disclose in the 510(k) process information that the FDA itself does not require.

In response, plaintiffs contend that their "fraud on the agency" claims impose requirements that are identical to those imposed under federal statutes and regulations. Br. in Opp. 18. This argument overlooks the fact that the FDA imposes an *objective* standard for statements of "intended use," which it determines from the proposed labeling, whereas plaintiffs' claims are premised on a *subjective* standard of intended use. Pet. 27; PLAC Br. 15-16; PhRMA Br. 10 ("[J]udging 'intended use' based on subjective intent is directly contrary to the federal regulatory scheme"). Plaintiffs have no answer to this point, and there is none.

c. Equally unpersuasive are plaintiffs' efforts to explain why their "fraud on the agency" claims are not *impliedly* preempted by federal law. Br. in Opp. 19-20. Plaintiffs fail to address the implied preemption analysis set forth in the petition (at 27-29) or the many cases that have concluded that "fraud on the agency" claims are impliedly preempted. See Pet. 12 n.5, 15-16; see also PhRMA Br. 12-17 ("fraud on the agency" claims would interfere with Congress's intent, reflected in recent legislation, to expedite the device approval process). In essence, plaintiffs fall back on the argument (refuted above) that their claim is no different from the design claim involved in *Medtronic*. Br. in Opp. 19-20.[6]

CONCLUSION

The petition for a writ of certiorari should be granted.

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[6] Plaintiffs make no effort to defend the Third Circuit's holding that tort law requirements of general applicability are excluded from preemption under the MDA.

Respectfully submitted.

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Supreme Court, U.S.
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No. 98-1768

In the Supreme Court of the United States

OCTOBER TERM, 1998

THE BUCKMAN COMPANY,

Petitioner,

v.

PLAINTIFFS' LEGAL COMMITTEE,

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Third Circuit

OPPOSITION TO MOTION OF DANEK MEDICAL, INC. FOR LEAVE TO FILE BRIEF AS *AMICUS CURIAE*

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OPPOSITION TO MOTION OF DANEK MEDICAL, INC. FOR LEAVE TO FILE BRIEF AS *AMICUS CURIAE*

Respondent, Plaintiffs' Legal Committee, hereby opposes the motion of Danek Medical, Inc. for leave to file a brief as *amicus curiae* in support of Buckman Company's petition for certiorari.

First, the Rules of this Court disfavor motions of this type. *Sup. Ct. R.* 37.2(b). The purpose of an *amicus curiae* brief is to "bring[ ] to the attention of the Court relevant matter not already brought to its attention by the parties." *Sup. Ct. R.* 37.1. "An *amicus curiae* brief that does not serve this purpose burdens the Court, and its filing is not favored." *Id.* A review of Danek's summary of argument reveals that the proposed *amicus* brief presents nothing new that is relevant to Buckman's petition. In fact, the legal preemption arguments contained in the two briefs are identical. Danek's motion, therefore, is an impermissible attempt by the parties to exceed the 30-page limitation imposed on Petitioner by *Sup. Ct. R.* 33.1(g)(i) for a petition for a writ of certiorari.[1]

Second, Danek's purported reason for filing an *amicus* brief is to "assist the Court in understanding the profound impact [on Danek] of allowing" plaintiffs' fraud-on-the-FDA claims to go forward. Danek Motion at 2. Danek has argued below, however, that the Third Circuit's decision does not impact on Danek in any way whatsoever because Danek was not a party in the *Buckman* appeal and because the *Buckman* appeal involved a different manufacturer. *See, e.g.*, Excerpts from briefs filed by Danek in the remand courts opposing Plaintiffs' motions to reinstate fraud-on-the-FDA claims in light of the Third Circuit's decision (appended hereto at 3a, 5a, 11a, 13a, 17a, 19a, 22a, 26a, 28a, 32a and 34a). In either event, Buckman already has argued in its petition that the Third Circuit's decision, as part of multidistrict proceedings, has "far-reaching legal and practical effects." Pet. at 16. The *amicus* brief adds no new relevant matter.

Third, in its attempt to have the Court grant certiorari, Danek presents collateral issues which pertain only to Danek and are not germane to Buckman. In doing so, Danek misstates the facts to which the Plaintiffs' Legal Committee has not had an opportunity to respond.

For these reasons, Danek's motion for leave to file a brief as *amicus curiae* should be denied.

Respectfully submitted,

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[1] Buckman's petition already consists of 30 full pages of argument.

APPENDIX

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Barbara Bruzer and Dale Eugene Bruzer,

Plaintiffs,

v.

Danek Medical, Inc., et al.

Defendants.

Civil Action No. 3-95-971 RHK/JMM

SOFAMOR DANEK DEFENDANTS' MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION TO REINSTATE A FRAUD-ON-THE-FDA CLAIM

INTRODUCTION

Plaintiffs' motion to reinstate the fraud-on-the-FDA claim dismissed by Judge Bechtle while this case was in MDL-1014 should be denied. Their analysis of In re Orthopedic Bone Screw Products Liability Litigation, 159 F.3d 817 (3d Cir. 1998) (hereafter "Buckman" decision), is flawed.[1] Ms. Bruzer's argument regarding Buckman as "law of the case" is simply wrong, and the Third Circuit decision is therefore not controlling here. Moreover, Buckman's holding that federal law does not preempt claims of misrepresentation directed to federal agencies is contrary to federal law on preemption as it has evolved in other courts both before and after Medtronic v. Lohr, 518 U.S. 470 (1996). Most importantly, plaintiffs cite neither the law nor the evidence that they would

[1] The Third Circuit recently denied Buckman's petition for rehearing. The defendants in Buckman have filed a stay motion which indicates that a petition for *certiorari* to the United States Supreme Court will be filed.

need, under Buckman[2], to pursue a fraud-on-the-FDA claim, and completely ignore this Court's prior observations on the absence of causation and reliance in connection with this claim.

1. Neither Minnesota Law Nor The Facts Of This Case Allow Plaintiffs To Reinstate the Fraud-On-The-FDA Claim.

Plaintiffs' fraud-on-the-FDA claim is premised on the notion that defendants allegedly defrauded the FDA by requesting a clearance from the FDA to market a medical device for a specific use while intending to unlawfully promote it for another use, thereby gaining access to the market. In her effort to sidestep Minnesota law and focus on activities which have never been the subject of enforcement action by the FDA, Ms. Bruzer suggests that she has a viable claim for fraud on a federal agency involving a medical device which was used here in both an on-label and off-label way by her surgeon, Dr. Garvey, even though Dr. Garvey's medical judgment was not influenced either by the FDA or the manufacturers.

The Buckman decision does not allow these plaintiffs to reinstate a fraud-on-the-FDA claim against different defendants under Minnesota law. Buckman expressly stated:

> Our holding is a narrow one. We do not hold that any of the plaintiffs have stated a claim under state law upon which relief could be granted.

159 F.3d at 829. Buckman, unlike other courts, held only that the FDCA did not preempt states from allowing fraud-on-the-FDA claims. Id. at 823-26. Even if Buckman's holding on preemption applies here (which it should not), plaintiffs must still establish that Minnesota would recognize such a claim, which they do not attempt to do.

To reinstate plaintiffs' fraud-on-the-FDA claim would require an Erie prediction of Minnesota law. Buckman provides no basis for such a prediction. Rather, "[a] federal court in di-

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[2] Plaintiffs also address, in their Notice of Supplemental Authority, the impact of Buckman and the FDA's Final Rule on their negligence per se claim. These arguments are wrong for the reasons set forth in section 4 of this memorandum.

versity is not free to engraft onto those state rules exceptions or modifications which may commend themselves to the federal court, but which have not commended themselves to the State in which the federal court sits." Day & Zimmerman, Inc v. Challoner, 423 U.S. 3, 4 (1975). See also, Karas v. American Family Insurance Co., 33 F.3d 995, 1000 (8th Cir. 1994) ("[a]s a federal court, our role is to interpret state law in diversity cases and not to fashion it"). There is no more basis after Buckman than before for predicting that Minnesota would allow a private plaintiff to pursue a claim for fraud supposedly committed against a federal agency where the device is used in both an on-label and off-label way by a surgeon whose judgment was unaffected by either the FDA's position on pedicle screw use or any activities of the defendants.

The facts in Bruzer are markedly different from the factual background considered in the Buckman decision. Buckman involved a different manufacturer that obtained a §510(k) clearance from the FDA for screws to be used in the long bones of the arms and legs and purportedly intended "at the time of the application to market that device solely for another, more hazardous use." Buckman, 159 F.3d at 828. The Third Circuit expressly recognized that such facts "bear[] no resemblance" to a dual-use situation where a manufacturer "disseminat[ed] . . . information relevant to off-label use" while doctors also employed the device "for the use intended." 159 F.3d at 828 and n.7.

Here, as is so with nine of the other cases before this Court, a "dual use" unquestionably existed. The FDA clearance here provided that the screws could be labeled and marketed for use in the sacrum[3]. Sacral use of screws is undeniably a common medical procedure[4]. Here, two screws

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[3] See FDA Clearance Letter (attached as Exhibits 1-3 to the Affidavit of Richard Treharne filed herein).

[4] See Recher Affidavit, Exhibit A (Surgeon Testimony Regarding Sacral Use).

were implanted in Ms. Bruzer's sacrum, the intended use for which clearance was granted, i.e., an on-label use. Dr. Garvey also implanted screws in the pedicles at L4 and L5, using the screws in a permissible off-label manner. Because the present facts do not resemble Buckman, the Third Circuit's decision does not entitle these plaintiffs to reinstate a fraud-on-the-FDA claim.

For a number of reasons, Minnesota law would not allow a fraud claim to proceed in these circumstances. Minnesota has consistently followed a course which does not allow private enforcement of statutes which do not provide for a private cause of action. The FDCA is such a law. See 21 U.S.C. §337(a). In reality, plaintiffs' fraud-on-the-FDA claim is a disguised "unlawful promotion" claim, which is premised upon the regulations of the FDA, the FDCA and the Medical Device Amendments (MDA's). As Danek has already pointed out, plaintiffs' attempt to pursue such claims under the FDCA under the guise of negligence per se is barred under Minnesota law. See Defendant's Summary Judgment Memorandum in Bruzer, pp. 22-23; see also Jeffers v. Convoy Co., 650 F.Supp. 315 (D.Minn. 1986); Valtakis v. Putnam, 504 N.W.2d 264, 266 (Minn. App. 1993). These cases lead to the conclusion that plaintiffs' unlawful promotion claim cannot be asserted under the guise of negligence per se when the statute sought to be used to establish a breach of duty does not provide for a private right of action. As plaintiffs' fraud-on-the-FDA claim is inextricably intertwined with the federal law regulating the medical device industry, it logically follows that Minnesota courts would not allow a claim for fraud on a federal agency when the claim is based upon a federal law which precludes private enforcement. Buckman expressly leaves to the transferor courts the issue of whether such a claim can be asserted under state law, and Minnesota would not recognize a claim of this sort.

Moreover, the statement of intended use made by Danek in its application for a marketing clearance was not untrue, and cannot be the basis for a fraud claim. Off-label use of medical devices

As Buckman does not apply to this case, and as Minnesota law would not recognize a fraud claim of this sort under the circumstances, plaintiffs' motion to reinstate this claim should be denied.

2. Plaintiffs Wrongly Assert that Buckman is the Law of the Case.

Because neither the facts nor the law allow plaintiffs to reinstate their fraud-on-the-FDA claim, they contend that "law of the case" prohibits this Court from making an independent ruling under Minnesota law. Pl. Br. at 3-5. This argument is meritless on several levels.

First, law of the case in multi-district litigation applies only to rulings that occur before an action is remanded. None of the cases on page 4 of plaintiffs' brief involve a decision made, as here, after remand. Once remand has taken place, any MDL jurisdiction that might have supported law of the case no longer exists. In re Upjohn Co. Antibiotic "Cleocin" Products Liability Litigation, 508 F.Supp. 1020, 1021 (E.D. Mich. 1981); Manual for Complex Litigation (3d) §31.133, at 255 (1995) (after remand, the transferor court has "exclusive jurisdiction and further proceedings in the [MDL] court with respect to a remanded case are not authorized").

Second, and more fundamentally, Danek was not a party in the Buckman appeal. Law of the case "does not apply to nonparties" who have not had their day in court. 4A C. Wright & A. Miller, Federal Practice & Procedure §4478, at 832 (Supp. 1998); see In re DG Acquisition Corp., 151 F.3d 75, 86 (2d Cir. 1998) ("[w]here there has been no review even though appeal has been taken, it is equivalent to the party not having had an opportunity to appeal, and prevents the challenged decision from becoming the law of the case").[7] Danek appeared only as *amicus curiae* in Buckman. 159 F.3d at 821 n.3. "[T]he filing of an amicus brief has never been enough to bind a non-party to the result

[7] Accord, e.g., Becherer v. Merrill Lynch, Pierce, Fenner & Smith, Inc., 43 F.3d 1054, 1070 (6th Cir. 1995); United States v. Guy, 903 F.2d 1240, 1242 (9th Cir. 1990); Gage v. General Motors Corp., 796 F.2d 345, 349 (10th Cir. 1986).

of a proceeding." Munoz v. County of Imperial, 667 F.2d 811, 816 (9th Cir.), cert. denied, 459 U.S. 825 (1982).[8]

Third, Judge Bechtle recognized that differences between the circuits on medical device preemption required each remand court to be free to apply its own circuit's law:

> If nothing else changes at this moment, if for example the Supreme Court entered an order on Lohr that remanded that case for some reason, the Court wouldn't change its ruling here. It would simply, on remand, tell the transferor court on the remand order, this Court has ruled in accordance with Third Circuit law that the following claims cannot be advanced. And **we would invite the transferor court to revisit that issue**. If that circuit binds that transferor court differently, that's not a difficult thing to do, that's an easy thing to do, the judge in the Eighth, First, or Fifth [Circuits] can say, thank you very mueh, Judge Bechtle. We feel differently in this circuit.

Recher Affidavit, Exhibit B; In re Orthopedic Bone Screw Products Liability Litigation, MDL-1014, (4/11/96) Hearing Tr. at 29-30 (E.D. Pa.) (emphasis added). For each of these reasons, law of the case is entirely inapplicable, and nothing obligates this Court to follow the Buckman decision.

3. **Claims of Fraud on a Federal Agency are Preempted under Federal Law.**

Several courts have already held, contrary to Buckman, that allegations attacking federal administrative decisions as "fraudulent" are preempted -- because such claims inherently conflict with whatever agency action they seek to invalidate. This conflict is particularly glaring since, as already discussed, the FDA's 1998 Final Rule (which was not before the Buckman court) rejected the same allegations made here.

Plaintiffs challenge the FDA's clearance allowing TSRH screws to be labeled and marketed for use in the sacrum. This administrative decision was not made in a vacuum, but was made in a

[8] Accord, e.g., Stryker v. Crane, 123 U.S. 527, 540 (1887); United States v. Michigan, 940 F.2d 143, 165 (6th Cir. 1991); Adams v. Bell, 711 F.2d 161, 197 n.128 (D.C. Cir. 1983), cert. denied, 465 U.S. 1021 (1984); TRW, Inc. v. Ellipse Corp., 495 F.2d 314, 318 (7th Cir. 1974); Boeing Airplane Co. v. Aeronautical Industrial District, 91 F. Supp. 596, 602 (W.D. Wash. 1950), aff'd, 188 F.2d 359 (9th Cir. 1951); 18 Wright & Miller, supra §4451, at 377-78 n. 15 (Supp. 1998); 4 Am. Jur. 2d, Amicus Curiae §6, at 327-28 & n. 43 (1995).

law. Under Minnesota law, there can be no negligence per se claim for promotional activities which allegedly violate federal law. Nothing in Buckman or the concept of federal preemption overrides Minnesota's policy of judicial restraint in such an instance.

CONCLUSION

For all of the above reasons, plaintiffs' motion to reinstate a claim of fraud-on-the-FDA is unsupported by any facts, contrary to law, and should therefore be denied.

Dated: February 22, 1999.

Respectfully submitted,

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IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO

DENISE ALMOND and JOHN ALMOND, Husband	:	
Plaintiffs,	:	C.A. No. C-1-94-755
v.	:	(Judge Herman J. Weber)
DANEK MEDICAL, INC.	:	
Defendant	:	

DEFENDANT DANEK MEDICAL, INC.'S BRIEF IN OPPOSITION TO PLAINTIFFS' MOTION FOR RELIEF FROM JUDGMENT DISMISSING FRAUD-ON-THE-FDA AND NEGLIGENCE PER SE CLAIMS

I. INTRODUCTION

Defendant Danek Medical Inc. opposes Plaintiffs' Motion for Relief From Judgment on the ground that the decision of the Court of Appeals for the Third Circuit on which it relies has no force or effect because the mandate is stayed pending a ruling on a petition for panel rehearing. In addition, even if the decision were to become the law of the Third Circuit, it would not be the law of this case and therefore would not be controlling, but at most persuasive authority. Finally, for a host of reasons, Danek is entitled to summary judgment on all claims irrespective of the reach of statutory preemption under the Medical Device Amendments. In particular, nothing in Buckman disturbs this Court's decision that Ohio would not allow recovery for negligence per se based upon alleged violations of the federal Food, Drug and Cosmetic Act ("FDCA").

This case was transferred to MDL-1014 on March 1, 1995. On March 28, 1997, Judge Bechtle dismissed all claims by MDL bone screw plaintiffs alleging fraud-on-the-FDA (PTO 845). Buckman Company, sued as a regulatory consultant to another manufacturer of medical

devices, Acro Med Corporation, had only fraud-on-the-FDA claims pending against it. PTO No. 900, entered by Judge Bechtle on May 12, 1997, dismissed such claims against Buckman. On September 12, 1997, Judge Bechtle certified the Buckman dismissal as a final order under Fed. R. Civ. P. 54(b) (PTO 1067). The MDL plaintiffs appealed dismissal of the fraud-on-the-FDA claim as to Buckman.

On November 17, 1998, a dividend panel of the Court of Appeals for the Third Circuit issued an opinion holding that Judge Bechtle had erred in ruling that the claim against Buckman was preempted by the FDCA. In re Orthopedic Bone Screw Products Liab. Litig., 159 F.3d 817 (3d Cir. 1998) ("Buckman"). On December 1, 1998, Buckman Company filed a timely petition for panel rehearing and suggestion of rehearing en banc. As of December 28, 1998, that petition remains pending. On December 2, 1998, Ms. Almond filed a Motion for Relief from Judgment explicitly based on the Third Circuit's Buckman decision.

In the meantime, this case was remanded from MDL-1014 to this Court on August 22, 1997, or well prior to the Buckman decision. On March 2, 1998, this Court entered its Amended Order granting partial summary judgment in favor of Danek. Among the claims dismissed were fraud-on-the-FDA and negligence per se. Design defect, inadequate warnings, and misrepresentation claims survived summary judgment.

II. ARGUMENT

A. PLAINTIFFS' MOTION FOR RELIEF FROM JUDGMENT IS PREMATURE

Plaintiffs' Rule 60(b) is based entirely on the Buckman opinion, but the Third Circuit's mandate has not yet issued in that case. Buckman's timely petition for panel rehearing

automatically stays the Third Circuit's mandate. A timely petition for rehearing pursuant to Fed. R. App. P. 40(a) automatically stays issuance of the mandate until issues raised by the petition are resolved. Fed. R. App. P. 41(a); Fine v. Bellefonte Underwriters Ins. Co., 758 F.2d 50, 53 (2d Cir. 1985). Until the Third Circuit's mandate issues, jurisdiction over the matter resides exclusively with the court of appeals. If the petition for rehearing is denied, the mandate will issue within seven days of the date of the order. Fed. R. App. P. 41. When the mandate issues, jurisdiction over the matter will be restored to the district court. Ostrer v. United States, 584 F.2d 594, 598 (2d Cir. 1978). See also 20 Moore's Federal Practice §341.12[2] at 341-7 (3d ed. 1998).

Plainly enough, Buckman has not changed Buckman's legal status vis-a-vis the plaintiffs who have sued it; until the mandate issues, if ever, those claims are dismissed. If Buckman is ineffective to change the rights of the litigants to the appeal in which the decision was rendered, and will remain so until the mandate issues, it can hardly have more effect on persons who were not parties to the appeal. In short, Buckman is of considerable interest for what it may portend, but at the moment it is not authority for doing anything, including reinstating claims that Judge Bechtle dismissed. Plaintiffs' motion for reinstatement is premature.

B. THE BUCKMAN DECISION IS NOT THE LAW OF THIS CASE

Plaintiffs argue Buckman as "law of this case." Br. at 3. Plaintiffs are wrong. First, this case was remanded before the Buckman appeal was even taken, let alone decided. "After remand, the transferor court has exclusive jurisdiction and further proceedings in the [MDL] court with respect to a remanded case are not authorized." Manual for Complex Litigation (3d) §31.133, at 255 (1995). Accordingly, the Third Circuit's post-remand decision thus "has no effect" here

except what this Court chooses to give it. In re Upjohn Co. Antibiotic "Cleocin" Products Liability Litigation, 508 F. Supp. 1020, 1021 (E.D. Mich. 1981).

More fundamentally, Buckman cannot be law of the case because Danek was not a party to the Buckman appeal.[4] Law of the case "does not apply to nonparties" who have not had their day in court. 4A C. Wright & A. Miller, Federal Practice & Procedure §4478, at 832 (Supp. 1998). "A review of the case law reveals that courts will refuse to apply virtual representation simply to preclude a nonparty from relitigating issues that have been lost after vigorous advocacy by a party who seems to hold an interest identical to the interests of the nonparty." Becherer v. Merrill Lynch, Pierce, Fenner & Smith, Inc., 43 F.3d 1054, 1070 (6th Cir. 1995).[5] The Buckman/AcroMed regulatory history is not the regulatory history of Danek's TSRH sacral screws, either as pleaded by plaintiffs or as the evidence will show. Hence the court of appeals' ruling as to Buckman did not decide the legal sufficiency of the complaint in this case, let alone whether plaintiffs' claims can withstand summary judgment scrutiny. Law of the case cannot apply, and Buckman is not controlling in this case.

C. THE BUCKMAN DECISION DOES NOT AFFECT PLAINTIFFS' NEGLIGENCE PER SE CLAIM

Plaintiffs erroneously argue that Buckman resuscitates their negligence per se claim. Negligence per se was not before the Third Circuit, and plaintiffs' negligence per se claims remain

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[4] Indeed, Danek attempted to participate as a party in the Buckman appeal, but was relegated to *amicus curiae* status upon plaintiffs' motion. 159 F.3d at 821, n.3.

[5] Accord, e.g., In re DG Acquisition Corp., 151 F.3d 75, 86 (2d Cir. 1998); United States v. Guy, 903 F.2d 1240, 1242 (9th Cir. 1990).

barred under Ohio law for all the reasons stated in Danek's summary judgment briefing.[1] The Third Circuit did not decide any state-law issues. 159 F.3d at 829 ("We do not hold that any of the plaintiffs have stated a claim under state law upon which relief could be granted."). It held only that the absence of a private right of action for violations of the FDCA or MDA and a provision conferring FDCA enforcement powers solely upon "the United States," were insufficient indicia of Congressional intent to preempt claims of fraud-on-the-FDA. Id. at 824-825. Buckman provides no grounds for relief from judgment here because Danek never asserted statutory preemption as a defense to negligence per se.

Buckman did not affect Ohio negligence per se law. Ohio does not treat statutory violations as negligence per se unless the statute contemplates private litigation of such violations. In Renfro v. Black, 52 Ohio St. 3d 27, 32, 556 N.E.2d 150, 155 (1990), the Ohio Supreme Court affirmed the trial court's refusal even to admit evidence of alleged FDCA violations because "there is no private civil cause of action for monetary recovery based upon alleged violations of the Federal Food, Drug and Cosmetic Act." The Supreme Court and the Sixth Circuit concur.[2]

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[1] See Defendant Danek Medical, Inc.'s Motion for Summary Judgment and Memorandum of Law in Support filed on January 2, 1998 and Danek Medical, Inc.'s Reply to Plaintiffs' Opposition to Summary Judgment filed on February 13, 1998.

[2] Medtronic, Inc. v. Lohr, 116 S. Ct. 2240, 2251 (1996) ("there is no explicit private cause of action against manufacturers contained in the MDA, and no suggestion that the Act created an implied private right of action"); Merrell Dow Pharm. Inc. v. Thompson, 478 U.S. 804, 812 n.10 (1986) ("where Congress has decided not to provide a particular federal remedy, we are not free to 'supplement' that decision in a way that makes it 'meaningless'") (citation omitted).

The Sixth Circuit stated, with respect to the FDCA, that a "state's ability to use a federal statute violation as a basis for state tort liability and negligence *per se* depends on the intent of Congress, and not merely on the intent of the state. . . . [T]he congressional decision not to provide a private cause of action under the FDCA becomes quite important in considering the propriety of a state negligence per se action for violation of the FDCA." In re Bendectin Litigation, 857 F.2d 290, 313-14 (6th Cir. 1988) (citation omitted), (continued...)

Spinal Systems 63 Fed. Reg. 40025 (FDA July 27, 1998).[1] The Final Rule demonstrates that the FDA investigated plaintiffs' fraud charges,[2] determined that prior screw clearances should be retained, and concluded that it was not defrauded.[3] The FDA's Final Rule defeats causation as a matter of law because it precludes any contention that, but for the alleged "fraud," the FDA might have done something materially different."The discussion in the Federal Register shows that the FDA concluded that it was never defrauded by the manufacturers of orthopedic bone screws. These claims have no merit." Estep v. Danek Medical, Inc., No. 1:96CV2580, slip op. at 12 (N.D. Ohio Oct. 5, 1998) (Exhibit A attached), reconsideration granted on other grounds (Dec. 8, 1998) (summary judgment entered against negligence per se) (Exhibit B attached). Cf. Stanton v. Astra Pharmaceutical Products, Inc., 718 F.2d 553 (F.2d 1983)(evidence of causation legally sufficient, if barely so, where four expert witnesses gave testimony from which the jury could have inferred that the FDA would have required notice to the medical community of adverse effects associated with defendant's drug if defendant had complied with requirement to report adverse reactions to drug).

Third, the Third Circuit specifically limited itself to fraud allegations against another manufacturer and did not consider Danek or its devices. Those allegations were that AcroMed

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[1] The FDA's Final Rule reclassified "pedicle screw spinal systems" from Class III to Class II devices for several indications, including one of Ms. Almond's specific problems – scoliosis. 63 Fed. Reg. at 40035.

[2] In December, 1995, Judge Bechtle permitted plaintiffs to submit their allegations to the FDA as public comments to the FDA's proposed reclassification of spinal implants. In re Orthopedic Bone Screw Products Liability Litigation, MDL-1014, 1995 WL 764580 (E.D. Pa. Dec. 14, 1995) (PTO 179).

[3] 63 Fed. Reg. at 40031, 40039 (pre-1995 clearances not misleading; continuing to use stated intended uses); id. at 40028-30 (cohort study and other data not falsified); at 40030 (rejecting allegations of undisclosed financial relationships); at 40032-33 (Danek 1/20/95 clearance not fraudulent).

intended "at the time of the application to market that device solely for another, more hazardous use." 159 F.3d at 828. That claim "bears no resemblance" to a dual-use situation where a manufacturer "disseminat[ed]. . .information relevant to off-label use" while doctors also employed the device "for the use intended." Id. at 828n.7 (emphasis added).

In this case it is undisputed that the broken screw allegations relate to bone screws implanted in Ms. Almond's sacrum. [9] It is also undisputed that TSRH screws had been cleared for use in the sacrum. [10] The undisputed facts here thus "bear[] no resemblance," id., to the fraud allegations in Buckman. Rather they demonstrate that the Danek's application for clearance to market the TSRH screws for sacral fixation was not "simply. . . a pretext." Id. at 820. Summary judgment against plaintiffs' fraud-on-the-FDA claim would thus be appropriate, even under Buckman. Ms. Almond's own surgery establishes that sacral fixation was a bona fide "intended use." There was no fraudulent misrepresentation to the FDA.

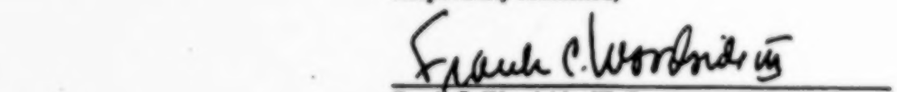
[9] See Defendant Danek Medical, Inc.'s Motion for Summary Judgment and Memorandum of Law (filed on January 2, 1998) at pp. 7 and 21 and Danek Medical, Inc.'s Reply to Plaintiffs' Opposition to Summary Judgment (filed on February 13, 1998) at pp. 2 and 11.

[10] TSRH screws were cleared for the "intended use" of sacral fixation beginning in 1989. FDA (4/6/89), (11/6/90), (12/10/90), (9/6/91), (12/2/91), (1/10/92), (1/22/92) clearance letters (Exhibits C - I attached).

III. CONCLUSION

For all of the reasons stated above, this Court should deny Plaintiffs' Motion for Relief from Judgment and sustain summary judgment in favor of Danek Medical, Inc. on the claims of fraud-on-the-FDA and negligence per se.

Respectfully submitted,



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UNITED STATES DISTRICT COURT FOR THE DISTRICT OF UTAH

CENTRAL DIVISION

----ooOoo----

SCOTT McCOLLIN and KAREN McCOLLIN, Plaintiffs, v. DANEK MEDICAL, INC., et al., Defendants.	DEFENDANTS' MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION TO REINSTATE A FRAUD-ON-THE-FDA CLAIM Case No. 2:95CV1097C

----ooOoo----

Defendants Danek Medical, Inc., Sofamor Danek Group, Inc., Sofamor, S.N.C., Sofamor, Inc. and Warsaw Orthopedic, Inc. (collectively, "Sofamor Danek"), submit this Memorandum in opposition to plaintiffs' Motion to Reinstate Plaintiff's Fraud-on-the-FDA claim.

I. Introduction

Plaintiffs' motion to reinstate the fraud-on-the-FDA claim dismissed by Judge Bechtle while this case was in MDL-1014 should be denied. Their analysis of In re Orthopedic Bone Screw Products Liability Litigation, 159 F.3d 817 (3d Cir. 1998) (hereafter "Buckman" decision), is flawed. Their argument regarding Buckman as "law of the case" is simply wrong.

Most importantly, plaintiffs cite neither the law nor the evidence they would need, under Buckman, to pursue a fraud-on-the-FDA claim.

II. Neither Utah Law Nor The Facts Of This Case Allow Plaintiffs To Reinstate Fraud On The FDA.

The Buckman decision does not allow these plaintiffs to reinstate a fraud-on-the-FDA claim against different defendants under the law of this jurisdiction. Buckman expressly stated:

> Our holding is a narrow one. We do not hold that any of the plaintiffs have stated a claim under state law upon which relief could be granted.

159 F.2d at 829. Buckman held only that the FDCA did not preempt states from allowing fraud-on-the-FDA claims. Id. at 823-26. But plaintiffs must still establish that Utah would recognize such a claim. Plaintiffs offer no such argument. Indeed, they ignore Utah law completely.[1]

To reinstate plaintiffs' fraud-on-the-FDA claim would require an Erie prediction of Utah law. Buckman provides no basis for such a prediction. Rather, "[a] federal court in diversity is not free to engraft onto those state rules exceptions or modifications which may commend themselves to the federal court, but which have not commended themselves to the State in which the federal court sits." Day & Zimmerman, Inc. v. Challoner, 423 U.S. 3, 4 (1975). "As a federal court, we are generally reticent to expand state law without clear guidance from its highest court."" Taylor v. Phelan, 9 F.3d 882, 887 (10th Cir. 1993).

There is no more basis after Buckman than before for predicting that Utah would allow plaintiffs to pursue fraud supposedly committed against the FDA.

The facts of this case also bar plaintiffs from reinstating fraud on the FDA at this late juncture. Buckman involved a different manufacturer that purportedly intended "at the time of

[1] The linchpin of the Third Circuit's generic state-law analysis, § 310 of the Restatement (Second) of Torts (see 159 F.3d at 826-27), has not been adopted in this state, and there is no precedent allowing fraud claims based upon statements allegedly made to a government agency.

the application to market that device solely for another, more hazardous use." Buckman, 159 F.3d at 828. The Third Circuit itself realized that such facts "bear[] no resemblance" to a dual-use situation where a manufacturer "disseminat[ed] . . . information relevant to off-label use" while doctors also employed the device "for the use intended." 159 F.3d at 828 & n.7.

The FDA clearance in this case involved sacral use—and sacral use of screws is undeniably a common medical procedure.[2] Because the present facts do not resemble Buckman, the Third Circuit's decision does not entitle these plaintiffs to reinstate a fraud-on-the-FDA claim.

Moreover, Buckman was limited to the pleadings and did not consider FDA's Final Rule on the Classification and Reclassification of Pedicle Screw Spinal Systems. 63 Fed. Reg. 40025 (FDA July 27, 1998) (Exh. C). The Final Rule demonstrates that the FDA investigated the same fraud charges, determined that prior screw clearances should be retained, and concluded that it was not defrauded.[3] The FDA expressly determined that the products involved in this case do not "present a substantial deception." Id. at 40035-36. Plaintiffs can never prove reliance or causation because the 1998 Final Rule eliminates any claim that, but for alleged "fraud," the FDA might have done something materially different. See Buckman, 159 F.3d at 827 (evidence that different FDA action would have prevented injury is part of "minimum quantum of evidence" necessary to make fraud-on-the-FDA claim). Thus, the "discussion in the Federal Register shows that the FDA concluded that it was never defrauded by the manufacturers of

[2] See FDA Clearance Letter (Exh. A); Surgeon Testimony Regarding Sacral Use (Exh. B).

[3] 63 Fed. Reg. at 40031 (item 8), 40039 (item 44) (pre-1995 clearances not misleading; continuing to use stated intended uses); id. at 40028-30 (items 1-3) (data not falsified); at 40030 (item 3) (rejecting allegations of undisclosed financial relationships); at 40032-33 (items 13-16) (Danek 1/20/95 clearance not fraudulent).

orthopedic bone screws. These claims have no merit." Estep v. Danek Medical, Inc., No. 1:96CV2580, slip op. at 12 (N.D. Ohio Oct. 5, 1998) (Exh. D).

III. Plaintiffs Wrongly Assert Law Of The Case.

Because neither the facts nor the law allow plaintiffs to reinstate fraud on the FDA, they contend that "law of the case" prohibits this Court from making an independent ruling under Utah law. Pl. br. at 3-5. This argument is meritless on several levels.

First, law of the case in multi-district litigation applies only to rulings that occur before an action is remanded. None of the cases on pages four-and five of plaintiffs' brief involve a decision made, as here, after remand. Once remand has taken place, any MDL jurisdiction that might have supported law of the case no longer exists. In re Upjohn Co. Antibiotic "Cleocin" Products Liability Litigation, 508 F. Supp. 1020, 1021 (E.D. Mich. 1981); Manual for Complex Litigation (3d) § 31.133, at 255 (1995).

Second, and most fundamentally, Sofamor Danek was not a party in the Buckman appeal. Law of the case "does not apply to nonparties" who have not had their day in court. 4A C. Wright & A. Miller, Federal Practice & Procedure § 4478, at 832 (Supp. 1998); see In re DG Acquisition Corp., 151 F.3d 75, 86 (2d Cir. 1998) ("Where there has been no review even though appeal has been taken, it is equivalent to the party not having had an opportunity to appeal, and prevents the challenged decision from becoming the law of the case.").[4] Danek appeared only as *amicus curiae* in Buckman. 159 F.3d at 821 n.3. "[T]he filing of an amicus brief has never been

[4] Accord, e.g., Becherer v. Merrill Lynch, Pierce, Fenner & Smith, Inc., 43 F.3d 1054, 1070 (6th Cir. 1995); United States v. Guy, 903 F.2d 1240, 1242 (9th Cir. 1990); Gage v. General Motors Corp., 796 F.2d 345, 349 (10th Cir. 1986).

enough to bind a non-party to the result of a proceeding." Munoz v. County of Imperial, 667 F.2d 811, 816 (9th Cir.), cert. denied, 459 U.S. 825 (1982).[5]

Finally, Judge Bechtle did not intend for preemption rulings in MDL-1014 to be law of the case. Quite the opposite, Judge Bechtle recognized that differences between the circuits on medical device preemption required each remand court to be free to apply its own circuit's law:

> If nothing else changes at this moment, if for example the Supreme Court entered an order on Lohr that remanded that case for some reason, the Court wouldn't change its ruling here. It would simply, on remand, tell the transferor court on the remand order, this Court has ruled in accordance with Third Circuit law that the following claims cannot be advanced. And **we would invite the transferor court to revisit that issue.** If that circuit binds that transferor court differently, that's not a difficult thing to do, that's an easy thing to do, the judge in the Eighth, First, or fifth [Circuits] can say, thank you very much, Judge Bechtle. We feel differently in this circuit.

In re Orthopedic Bone Screw Products Liability Litigation, MDL-1014 (4/11/96) Hearing Tr. at 29-30 (E.D. Pa.) (emphasis added) (Exh. E). For each of these reasons, law of the case is entirely inapplicable, and nothing obligates this Court to follow the Buckman decision.

IV. Conclusion

For all of the above reasons, plaintiffs' motion to reinstate a claim of fraud on the FDA is unsupported by any facts and is contrary to law, and should therefore be denied.

DATED this 11th day of February, 1999.

RAY, QUINNEY & NEBEKER

Paul S. Felt
Joni J. Jones
Attorneys for Defendants

[5] Accord, e.g., Stryker v. Crane, 123 U.S. 527, 540 (1887); United States v. Michigan, 940 F 2d 143, 165 (6th Cir. 1991); Adams v. Bell, 711 F.2d 161, 197 n.128 (D.C. Cir. 1983), cert. denied, 465 U.S. 1021 (1984); TRW, Inc. v. Ellipse Corp., 495 F.2d 314, 318 (7th Cir. 1974); Boeing Airplane Co. v. Aeronautical Industrial District, 91 F. Supp. 596, 602 (W.D. Wash. 1950), aff'd, 188 F.2d 359 (9th Cir. 1951); 18 Wright & Miller, supra § 4451, at 377-78 n.15 (Supp 1998); 4 Am. Jur. 2d, Amicus Curiae § 6, at 327-28 & n.43 (1995).

UNITED STATES DISTRICT COURT
DISTRICT OF MARYLAND
(Northern Division)

JOSEPH STRANGE,

Plaintiff,

v.

SOFAMOR DANEK GROUP, INC., et al.,

Defendants.

Civil Action No. Y 95-3193

DANEK DEFENDANTS' MEMORANDUM IN OPPOSITION TO PLAINTIFF'S MOTION TO REINSTATE FRAUD-ON-THE-FDA CLAIM

Defendants, Sofamor Danek Group, Inc. Danek Medical Inc., Warsaw Orthopedic, Inc., Sofamor Inc., and Sofamor S.N.C. (hereinafter "Danek" or "Danek Defendants"), respectfully submit this Memorandum in Opposition to Plaintiff's Motion to Reinstate Plaintiff's "Fraud-on-the-FDA" Claim.

I. INTRODUCTION

In November 1998, Plaintiff filed with this Court a "Notice of Recent Authority" purportedly affecting Danek Defendants' entitlement to summary judgment on Plaintiff's negligence per se claim and Plaintiff's then dismissed claim for "Fraud-on-the-FDA." In support of that pleading, Plaintiff relied on the then recent opinion of the Third Circuit in In re Orthopedic Bone Screw Products Liability Litigation, 159 F.3d 817 (3d Cir. 1998) (hereinafter "Buckman" decision), which held, over a dissenting opinion and contrary to the decisions of several other Circuits, that the Medical Device Amendments of the Federal Food, Drug and

Circuit's decision. Pl.'s Memo. in Supp. of Mot. at 3-5. This argument is meritless on several levels.

First, law of the case in multi-district litigation applies only to rulings that occur before an action is remanded. None of the cases cited by Plaintiff involve a decision made, as here, after remand. See, Pl.'s Memo. In Supp. Of Mot. at 4. Once remand has taken place, any MDL jurisdiction that might have supported law of the case no longer exists. In re Upjohn Co. Antibiotic "Cleocin" Products Liability Litigation, 508 F. Supp. 1020, 1021 (E.D. Mich. 1981); Manual for Complex Litigation (3d) §31.133, at 255 (1995). See generally 15 C. WRIGHT, A. MILLER & E. COOPER, FEDERAL PRACTICE AND PROCEDURE, § 3862 at 508-9 and n.30 ("Of course, once a case has been remanded to the transferor district and a final judgment has been entered, any appeal may include objections to errors allegedly committed by the transferee judge.")

Second, and more fundamentally, Danek Defendants were not parties in the Buckman appeal. Law of the case "does not apply to nonparties" who have not had their day in court. 4A C. WRIGHT & A. MILLER, FEDERAL PRACTICE AND PROCEDURE §4478, at 832 (Supp. 1998); see In re DG Acquisition Corp., 151 F.3d 75, 86 (2d Cir. 1998) ("[w]here there has been no review even though appeal has been taken, it is equivalent to the party not having had an opportunity to appeal, and prevents the challenged decision from becoming the law of the case").[1] Danek appeared only as *amicus curiae* in Buckman. 159 F.3d at 821 n.3. "[T]he filing

[1] Accord, e.g., Rechsteiner v. Merrill Lynch, Pierce, Fenner & Smith, Inc., 43 F.3d 1054, 1070 (6th Cir. 1995); United States v. Orr, 903 F.2d 1240, 1242 (9th Cir. 1990); Gass v. General Motors Corp., 796 F.2d 345, 349 (10th Cir. 1986).

of an amicus brief has never been enough to bind a non-party to the result of a proceeding." Munoz v. County of Imperial, 667 F.2d 811, 816 (9th Cir.), cert. denied, 459 U.S. 825 (1982).[2]

Third, Judge Bechtle did not intend for preemption rulings in MDL-1014 to be law of the case. Quite the opposite, Judge Bechtle recognized that differences between the circuits on medical device preemption required each remand court to be free to apply its own circuit's law:

> If nothing else changes at this moment, if for example the Supreme Court entered an order on Lohr that remanded that case for some reason, the Court wouldn't change its ruling here. It would simply, on remand, tell the transferor court on the remand order, this Court has ruled in accordance with Third Circuit law that the following claims cannot be advanced. And **we would invite the transferor court to revisit that issue.** If that circuit binds that transferor court differently, that's not a difficult thing to do, that's an easy thing to do, the judge in the Eighth, First, or Fifth [Circuits] can say, thank you very much, Judge Bechtle. We feel differently in this circuit.

In re Orthopedic Bone Screw Products Liability Litigation, MDL-1014, (4/11/96) Hearing Tr. at 29-30 (E.D. Pa.) (emphasis added)[3]. For each of these reasons, the doctrine of law of the case is entirely inapplicable, and nothing obligates this Court to follow the Buckman decision.

2. ***Fraud On The FDA Is Preempted.*** Although the Fourth Circuit has not addressed this issue precisely, the other federal circuits that have considered these issues - the Fifth, Seventh, and Eleventh Circuits - have already held, contrary to Buckman, that allegations attacking federal administrative decisions as "fraudulent" are preempted because such claims inherently conflict with whatever agency action they seek to invalidate. See Reeves v.

[2] Accord, e.g., Stryker v. Crane, 123 U.S. 527, 540 (1887); United States v. Michigan, 940 F.2d 143, 165 (6th Cir. 1991); Adams v. Bell, 711 F.2d 161, 197 n.128 (D.C. Cir. 1983), cert. denied, 465 U.S. 1021 (1984); D.R.W., Inc. v. Fluor Corp., 495 F.2d 314, 318 (7th Cir. 1974); Boeing Airplane Co. v. Aeronautical Industrial District, 91 F. Supp. 596, 602 (W.D. Wash. 1950), aff'd, 188 F.2d 359 (9th Cir. 1951); 18 Wright & Miller, supra §4451, at 377-78 n. 15 (Supp. 1998); 4 Am. Jur. 2d, Amicus Curiae §4, at 327-28 & n. 43 (1995).

[3] For the Court's convenience, a copy of the applicable portion of this transcript is attached hereto and incorporated herein by reference as Exhibit A.

BEST AVAILABLE COPY

III. CONCLUSION

For the reasons stated herein, and for the reasons stated in Danek Defendants Memorandum of Law in Support of Motion for Summary Judgment, Danek's Reply to Plaintiff's Opposition to that Motion, and Danek Defendants' Memorandum in Opposition to Plaintiff's Notice of Recent Authority, Plaintiff's Motion to Reinstate his Fraud on the FDA claim should be denied.

Respectfully submitted,

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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF INDIANA
HAMMOND, INDIANA

EDWARD M. PARKS, Plaintiff, vs. DANEK MEDICAL, INC., Defendant.	)	Cause No. 2:95 CV 206

DEFENDANT'S MEMORANDUM IN OPPOSITION TO PLAINTIFF'S MOTION TO REINSTATE A FRAUD-ON-THE-FDA CLAIM

Plaintiff's motion to reinstate the fraud-on-the-FDA claim dismissed by Judge Bechtle while this case was in MDL-1014 should be denied. First, Plaintiff's analysis of In re Orthopedic Bone Screw Products Liability Litigation, 159 F.3d 817 (3d Cir. 1998) (hereafter "Buckman" decision), is flawed. Second, Plaintiff's argument regarding Buckman as "law of the case" is simply wrong, and Buckman is contrary to controlling precedent in this circuit. Most importantly, Plaintiff cites neither the law nor the evidence that he would need, under Buckman, to pursue a fraud-on-the-FDA claim.

I. Neither Indiana Law Nor The Facts Of This Case Allow Plaintiff To Reinstate Fraud On The FDA.

The Buckman decision does not allow Plaintiff in this case to reinstate a fraud-on-the-FDA claim against different defendants under the law of this jurisdiction. Buckman expressly stated:

> Our holding is a narrow one. We do not hold that any of the plaintiffs have stated a claim under state law upon which relief could be granted.

159 F.2d at 829. Buckman held only that the FDCA did not preempt states from allowing fraud-on-the-FDA claims. Id. at 823-26. Plaintiff must still establish that Indiana would recognize such a claim. But, Plaintiff offers no such argument. Indeed, he ignores Indiana law completely.[1]

To reinstate Plaintiff's fraud-on-the-FDA claim would require an Erie prediction of Indiana law. Buckman provides no basis for such a prediction. Rather, "[a] federal court in diversity is not free to engraft onto those state rules exceptions or modifications which may commend themselves to the federal court, but which have not commended themselves to the State in which the federal court sits." Day & Zimmerman, Inc. v. Challoner, 423 U.S. 3, 4 (1975). "When we are faced with opposing plausible interpretations of state law, we generally choose the narrower interpretation which restricts liability." Birchler v. Gehl Co., 88 F.3d 518, 521 (7th Cir. 1996). "Plaintiffs seeking to bring novel state law claims should present those claims initially in state court." Shields Enterprises, Inc. v. First Chicago Corp., 975 F.2d 1290, 1298 (7th Cir. 1992) (citations and quotation marks omitted). Thus, there is no more basis after Buckman than before for predicting that Indiana would allow Plaintiff to pursue fraud supposedly committed against the FDA.

The facts of this case also bar Plaintiff from reinstating fraud on the FDA at this late juncture. Buckman involved a different manufacturer that purportedly intended "at the time of the application to market that device solely for another, more hazardous use." Buckman,

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[1]The linchpin of the Third Circuit's generic state-law analysis, §310 of the Restatement (Second) of Torts (see 159 F.3d at 826-27), has not been adopted in this state, and there is no precedent allowing fraud claims based upon statements allegedly made to a government agency.

159 F.3d at 828. The Third Circuit itself realized that such facts "bear[] no resemblance" to a dual-use situation where a manufacturer "disseminat[ed]...information relevant to off-label use" while doctors also employed the device "for the use intended." 159 F.3d at 828 & n.7.

The FDA clearance in this case involved sacral use -- and sacral use of screws is undeniably a common medical procedure.[2] Because the present facts do not resemble Buckman, the Third Circuit's decision does not entitle these plaintiffs to reinstate a fraud-on-the-FDA claim.

Moreover, Buckman was limited to the pleadings and did not consider FDA's Final Rule on the Classification and Reclassification of Pedicle Screw Spinal Systems. 63 Fed. Reg. 40025 (FDA July 27, 1998) (Exh. C). The Final Rule demonstrates that the FDA investigated the same fraud charges, determined that prior screw clearances should be retained, and concluded that it was not defrauded.[3] The FDA expressly determined that the products involved in this case do not "present a substantial deception." Id. at 40035-36. Plaintiff can never prove reliance or causation because the 1998 Final Rule eliminates any claim that, but for alleged "fraud," the FDA might have done something materially different. See Buckman, 159 F.3d at 827 (evidence that different FDA action would have prevented injury is part of "minimum quantum of evidence" necessary to make fraud-on-the-FDA

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[2]See FDA Clearance Letter (Exh. A); Surgeon Testimony Regarding Sacral Use (Exh. B).

[3]63 Fed. Reg. at 40031 (item 8), 40039 (item 44) (pre-1995 clearances not misleading; continuing to use stated intended uses); id. at 40028-30 (items 1-3) (data not falsified); at 40030 (item 3) (rejecting allegations of undisclosed financial relationships); at 40032-33 (items 13-16) (Danek 1/20/95 clearance not fraudulent). See also Defendant's Reply Brief in Support of Motion for Summary Judgment, page 20.

claim). Thus, the "discussion in the Federal Register shows that the FDA concluded that it was never defrauded by the manufacturers of orthopedic bone screws. These claims have no merit." Estep v. Danek Medical, Inc., No. 1:96CV2580, slip op. at 12 (N.D. Ohio Oct. 5, 1998) (Exh. D).

II. Plaintiff Wrongly Asserts Law Of The Case.

Because neither the facts nor the law allows Plaintiff to reinstate fraud on the FDA, he contends that "law of the case" prohibits this Court from making an independent ruling under Indiana law. Pl. br. at 3-5. This argument is meritless on several levels.

First, law of the case in multi-district litigation applies only to rulings that occur before an action is remanded. None of the cases on page four (4) of Plaintiff's brief involve a decision made, as here, after remand. Once remand has taken place, any MDL jurisdiction that might have supported law of the case no longer exists. In re Upjohn Co. Antibiotic "Cleocin" Products Liability Litigation, 508 F. Supp. 1020, 1021 (E.D. Mich. 1981); Manual for Complex Litigation (3d) §31.133, at 255 (1995).

Second, and more fundamentally, Danek was not a party in the Buckman appeal. Law of the case "does not apply to nonparties" who have not had their day in court. 4A C. Wright & A. Miller, Federal Practice & Procedure §4478, at 832 (Supp. 1998). See also In re DG Acquisition Corp., 151 F.3d 75, 86 (2d Cir. 1998) ("[w]here there has been no review even though appeal has been taken, it is equivalent to the party not having had an opportunity to

appeal, and prevents the challenged decision from becoming the law of the case").[4] Danek appeared only as *amicus curiae* in Buckman. 159 F.3d at 821 n.3. "[T]he filing of an amicus brief has never been enough to bind a non-party to the result of a proceeding." Munoz v. County of Imperial, 667 F.2d 811, 816 (9th Cir.), cert. denied, 459 U.S. 825 (1982); TRW, Inc. v. Ellipse Corp., 495 F.2d 314, 318 (7th Cir. 1974).[5]

Third, Judge Bechtle recognized that differences between the circuits on medical device preemption required each remand court to be free to apply its own circuit's law:

> If nothing else changes at this moment, if for example the Supreme Court entered an order on Lohr that remanded that case for some reason, the Court wouldn't change its ruling here. It would simply, on remand, tell the transferor court on the remand order, this Court has ruled in accordance with Third Circuit law that the following claims cannot be advanced. And we would invite the transferor court to revisit that issue. If that circuit binds that transferor court differently, that's not a difficult thing to do, that's an easy thing to do, the judge in the Eighth, First, or Fifth [Circuits] can say, thank you very much, Judge Bechtle. We feel differently in this circuit.

In re Orthopedic Bone Screw Products Liability Litigation, MDL-1014, (4/11/96) Hearing Tr. at 29-30 (E.D. Pa.) (emphasis added) (Exh. E). For each of these reasons, law of the case is entirely inapplicable, and nothing obligates this Court to follow the Buckman decision.

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[4] Accord, e.g., Becherer v. Merrill Lynch, Pierce, Fenner & Smith, Inc., 43 F.3d 1054, 1070 (6th Cir. 1995); United States v. Guy, 903 F.2d 1240, 1242 (9th Cir. 1990); Gage v. General Motors Corp., 796 F.2d 345, 349 (10th Cir. 1986).

[5] Accord, e.g., Stryker v. Crane, 123 U.S. 527, 540 (1887); United States v. Michigan, 940 F.2d 143, 165 (6th Cir. 1991); Adams v. Bell, 711 F.2d 161, 197 n.128 (D.C. Cir. 1983), cert. denied, 465 U.S. 1021 (1984); Boeing Airplane Co. v. Aeronautical Industrial District, 91 F. Supp. 596, 602 (W.D. Wash. 1950), aff'd, 188 F.2d 359 (9th Cir. 1951); 18 Wright & Miller, supra §4451, at 377-78 n. 15 (Supp. 1998); 4 Am. Jur. 2d, Amicus Curiae §6, at 327-28 & n. 43 (1995).

v. Upjohn Co., 985 F.2d 516, 518-19 (11th Cir.) (same; fraud on the Environmental Protection Agency), cert. denied, 510 U.S. 913 (1993).

As Mitchell held, nothing in Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996), requires a different result. A majority of the court in Medtronic specifically recognized that preemption could occur by virtue of direct conflict. Id. at 503, 507-08. Even Buckman "d[id] not rule out the possibility that there may be some areas of preemption. . .based on clear and direct conflicts between the requirements of state law and those of the FDCA." 159 F.3d at 826.[6] Under Mitchell, preemption is another ground upon which plaintiffs' attempt to reinstate fraud on the FDA must fail.

IV. Conclusion

For all of the above reasons, Plaintiff's motion to reinstate a claim of fraud on the FDA is unsupported by any facts, contrary to law, and should therefore be denied.

Respectfully submitted,

Robert F. Wagner, #1066-49

Dina M. Cox, #18590-49

[6]The most serious flaw in the Buckman court's reasoning was its reliance upon a portion of the Medtronic decision that did not command a majority of the Supreme Court. See 159 F.3d at 825 (following Medtronic, 518 U.S. at 487 (plurality)). In "splintered" Supreme Court decisions, however, "the holding of the Court may be viewed as that position taken by those Members who concurred in the judgment on the narrowest grounds." Marks v. United States, 430 U.S. 188, 193 (1977).

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF VIRGINIA
Roanoke Division

LEILA HARTWELL WILLIAM G. HARTWELL and JENNIFER STILL ROBERT STILL	)	
Plaintiffs,	)	
v.	)	Civil Action No. 95-1134-R
DANEK MEDICAL, INC., et al.,	)	
Defendants.	)	

DEFENDANTS' SUPPLEMENTAL MEMORANDUM REGARDING PLAINTIFFS' CLAIMS OF FRAUD-ON-THE-FDA

Pursuant to the Court's instruction at the November 19, 1998 hearing, defendants Danek Medical, Inc., Sofamor Danek Group, Inc., Sofamor, Inc. and Sofamor, S.N.C. (collectively "Danek") submit this brief to address the Third Circuit's recent decision reversing the dismissal of a fraud-on-the-FDA claim against the Buckman Company in the MDL proceedings. In re: Orthopedic Bone Screw Products Liab. Litig., 1998 WL 793200 (3d Cir. Nov. 17, 1998) (attached as Exh. A). As set out below, the Third Circuit decision is not binding on this Court, is contrary to Virginia law and Fourth Circuit precedent, and is factually inapposite. Moreover, plaintiffs cannot establish that any alleged fraudulent representations by Danek caused their injuries. As a result, this Court should deny any motion by the plaintiffs to reinstate their claim of fraud-on-the-FDA or to reconsider Judge Bechtle's decision dismissing that claim and enter summary judgment in favor of Danek on all claims.

impossible to predict, from the bare pleadings, that no state in the country would allow a fraud-on-the-FDA claim under state law. Id. *11-*13.

Significantly, the Third Circuit's decision dealt only with a claim of fraud-on-the-FDA against the Buckman Company. Orthopedic Bone Screw, 1998 WL 793200 at *2 ("Buckman is a regulatory consultant. . .retained by AcroMed").[1] Thus, it does not address allegations relating to Danek or its devices. Moreover, the Court itself pointed out the limited nature of its decision:

> Our holding is a narrow one. ***We do not hold that any of the plaintiffs have stated a claim under state law upon which relief could be granted.*** Neither we nor the district court is in a position to do that before identifying, with the help of the parties, the governing law or laws. Rather, we hold that (1) the plaintiffs' "fraud on the FDA" theory of liability is not so at odds with traditional principles of tort law that Buckman is entitled to a dismissal of all claims against it at this stage; and (2) if the state law of fraudulent misrepresentation applicable in one or more of these cases would impose liability on Buckman in the circumstances alleged, that law would not be preempted by the MDA.

Orthopedic Bone Screw, 1998 WL 793200 at *14 (emphasis added). In addition, the Third Circuit's decision is not final. The Buckman Company will seek re-hearing *en banc*, and, if that is unsuccessful, a review by the Supreme Court.

While the Third Circuit's decision theoretically opens the way for this Court to consider reinstatement of plaintiffs' fraud-on-the-FDA claim, it does not prevent judgment in favor of Danek in this case. This case is no longer part of MDL-1014, thus the Third Circuit's

[1] For this reason, neither Sofamor nor Danek were permitted to participate in the appeal, except as *amicus curiae*. Id. *4 n.3.

decision is not binding on this Court,[2] and any appeal by Hartwell or Still of Judge Bechtle's decision in PTO 845 would be heard by the Fourth Circuit on appeal from this Court.

If plaintiffs move to reinstate their fraud-on-the-FDA claim or move the Court to reconsider Judge Bechtle's ruling in PTO 845, the Court should deny such a motion notwithstanding the Third Circuit's recent decision. First, the Third Circuit's decision does not purport to decide any issues of state law, id. *5 (state law "issues are not before us"), and Virginia does not recognize a claim for fraud-on-the-FDA. Second, the Third Circuit did not address the 1998 FDA Final Rule, id. *4-5, in which the FDA made clear that it had not been defrauded. Third, while a decision of the Third Circuit might usually be of persuasive authority to this Court, the authority of this decision is undermined by the "vehement" dissent, by conflicting authority in the Fourth Circuit and by the significant factual differences present in this case. Finally, it is undisputed that, unlike the AcroMed screws at issue in the Third Circuit case, the TSRH Device was lawfully on the market for sacral use. In both of plaintiffs' surgeries, Dr. Leipzig used the Device for sacral, as well as lumbar, fixation. Since Dr. Leipzig used the Device for its on-label purpose of sacral fixation and since he was unaware of the FDA status of the Device at the time of Hartwell's and Still's surgeries, plaintiffs cannot prove that he used the Device as the result of any alleged fraud-on-the-FDA.

[2] Cf. Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach, 118 S. Ct. 956, 963-64 (1998) (MDL judge without power to assign any part of remanded MDL case to himself).

approved by the FDA." Id. at 1139. The Court declined to interpret the Lanham Act as allowing private assertion of FDCA violations. Id. As in Mylan, Hartwell and Still cannot "by ingenious pleading" escape the FDCA's bar against private enforcement "by making it appear that another not truly appropriate rule is applicable." Id.

Moreover, the Third Circuit decision was based on allegations materially different from those in this case. In the Third Circuit case, plaintiffs alleged that AcroMed represented to the FDA that its screws were intended for use in the "long bones" of the body, even though the screws were marketed and used exclusively in the spine. Orthopedic Bone Screw, 1998 WL 793200 at *5.[4] Here, on the other hand, plaintiffs' allege only that Danek falsely represented to the FDA that the Device was intended for sacral application. Amended Complaint, ¶¶ 102-104, 108. Unlike Buckman and AcroMed, Danek obtained clearance to label and market the TSRH Device for labeling and marketing for a variety of spinal indications, including fixation by bone screws to the pedicles of the sacrum. Further, in both Hartwell's and Still's surgeries, Dr. Leipzig used the Device for sacral fixation. Dr. Leipzig's on-label use of the Device effectively rebuts the claim that Danek's fraudulently obtained clearance of the Device for sacral use merely as a pretext to enable it to market the Device for lumber use. Thus, the facts alleged here are within the distinction recognized by the Third Circuit which stated:

> the situation here alleged bears no resemblance to one in which an applicant for a §510(k) clearance intends to market its device for the use represented, subsequently markets for that use, and, at the same time, responds to direct requests for information from physicians concerning off-label use.

Id. at *18 n.7.

[4] Likewise, in its comments to the FDA regarding the Final Rule, the Plaintiffs' Legal Committee focuses on AcroMed, not Danek. Those comments do not reference any false representations by Danek to the FDA. See *Comments of the Plaintiffs Legal Committee in In re Orthopedic Bone Screw Litigation, MDL Docket 1014, Concerning Proposed Rulemaking* at 34-39; 49-50 (attached as Exh. D).

IV. THE ALLEGED FRAUD DID NOT CAUSE ANY INJURIES TO PLAINTIFFS.

To establish a causative link between the alleged fraud and their surgery, Hartwell and Still claim that if Danek had not fraudulently claimed that the Device was intended for sacral use, the Device would not have been on the market for Dr. Leipzig to use. Amended Complaint, ¶¶ 109, 120. Thus, plaintiffs must prove that but for the alleged fraudulent conduct, the Device would not have been on the market. As a matter of law, plaintiffs cannot meet this burden. First, in the Final Rule, the FDA rejected comments that pedicle screw spinal systems should not be allowed on the market for any use. 63 Fed. Reg. at 40035.

Second, plaintiffs do not allege that the FDA improperly cleared the Device for sacral use. Rather, they claim only that Danek's representations to the FDA regarding the intended use of the Device in the sacrum were false. See Complaint, ¶ 108. Thus, regardless of the alleged fraud, the Device was properly on the market for sacral applications. In both of plaintiff's surgeries, Dr. Leipzig used the Device in the sacrum, conclusively establishing that Danek's request for § 510(k) clearance for sacral use was not merely a pretext to allow Danek to market the Device. Further, Dr. Leipzig did not know the FDA status of the Device at the time of plaintiffs' surgeries. As a result, even assuming that Danek's statements to the FDA about the intended purpose of the Device were fraudulent, the Device would still have been on the market,

and Dr. Leipzig would still have used the Device in plaintiffs' surgeries.[5] As a result, plaintiffs cannot prove that Dr. Leipzig used the Device as the result of any allegedly fraudulent conduct.

CONCLUSION

For the foregoing reasons, defendants respectfully requests that the Court enter summary judgment in their favor on all of the claims asserted by Hartwell and Still and deny any motion to reinstate Count I or to reconsider Judge Bechtle's decision in PTO 845.

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[5] Since learning the regulatory status of the screws, Dr. Leipzig has not changed his practice style and would not have changed his recommended treatment for Hartwell or Still. Deposition of Dr. James Leipzig at 36-37.

No. 98-1768

In the Supreme Court of the United States

OCTOBER TERM, 1998

THE BUCKMAN COMPANY,

Petitioner,

v.

PLAINTIFFS' LEGAL COMMITTEE,

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Third Circuit

CERTIFICATE OF SERVICE

I, Michael D. Fishbein, counsel for Respondent and a member of the Bar of this Court, hereby certify that on this 4th day of June, 1999, I caused three copies of the Opposition to Motion of Danek Medical, Inc. For Leave to File Brief as *Amicus Curiae* in the above-captioned case to be served on the following counsel of record:

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No. 98-1768

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Supreme Court of the United States

THE BUCKMAN COMPANY,
Petitioner,

v.

PLAINTIFFS' LEGAL COMMITTEE,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Third Circuit

MOTION FOR LEAVE TO FILE BRIEF AMICUS CURIAE AND BRIEF FOR PRODUCT LIABILITY ADVISORY COUNCIL, INC., IN SUPPORT OF THE PETITION

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IN THE

Supreme Court of the United States

No. 98-1768

THE BUCKMAN COMPANY,
Petitioner,
v.
PLAINTIFFS' LEGAL COMMITTEE,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Third Circuit

MOTION FOR LEAVE TO FILE BRIEF AMICUS CURIAE

Pursuant to Rule 37.2 of the Rules of this Court, the Product Liability Advisory Council, Inc. ("PLAC"), moves for leave to file the accompanying brief as *amicus curiae* in support of the petition for a writ of certiorari. Counsel for Petitioner has consented to the filing of the brief, but counsel for Respondent has withheld consent.

PLAC is an association of industrial companies that was formed for the principal purpose of submitting *amicus curiae* briefs in appellate cases involving significant issues affecting the law of product liability. Its members include manufacturers of a wide variety of products, including motor vehicles, pharmaceuticals, medical devices, pesticides, boats, aircraft, foodstuffs, and chemicals, who are governed by comprehensive federal safety regulations

and statutes, including statutes with preemption provisions. PLAC and its members therefore have a strong interest in the proper resolution of conflicts between the requirements of federal statutes and regulations, on the one hand, and state tort law, on the other.

Here, regulations promulgated by the Food and Drug Administration ("FDA") pursuant to the Medical Device Amendments of 1976 ("MDA")[1] specified the categories of information that a device manufacturer must provide to the FDA when applying for clearance to market a medical device. Those regulations did not state that the application must notify the FDA of the manufacturer's subjective intent regarding possible post-approval "off-label" uses[2] to which physicians might put the device. Instead, the regulations required the manufacturer to submit marketing materials that the manufacturer proposed to use to inform the medical community about the intended use of the device—specifically, "[p]roposed labels, labeling, and advertisement sufficient to describe the device, its intended use, and the directions for its use." 21 C.F.R. § 807.87 (1986).

Nevertheless, the court of appeals held that federal law neither expressly nor impliedly preempts a common-law fraud claim alleging that, in connection with an application for FDA clearance to market certain surgical screws,

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[1] Pub. L. No. 94-295, 90 Stat. 539 (1976) (codified as amended in scattered sections at 21 U.S.C. §§ 360c *et seq.*).

[2] "Off-label" uses are uses of medical devices by physicians for purposes other than the intended uses specified in the devices' labeling approved by the FDA. Pet. App. 28a-29a (Cowen, J., dissenting). As Judge Cowen stated, "The FDA and the medical community have long recognized the importance of doctors' off-label uses of medical products. . . . Doctors may, in the exercise of their professional judgment, decide that based on current medical research an unapproved use of a product best serves a patient's needs." *Id.* at 29a.

Petitioner and its manufacturer client deceived the FDA by failing to tell it their subjective intent regarding post-clearance "off-label" uses. Under that holding, the individual states are free to maintain and enforce state standards that require manufacturers to provide to the FDA not only the information that the FDA itself considers necessary or useful in determining whether to permit a device to be marketed, but additional categories of information that state courts and juries decide should have been provided to the FDA under *their* interpretation of the MDA and FDA regulations. Moreover, that holding permits such state standards to be enforced in state fraud actions in addition to, and independent of, any claim seeking compensation based on allegations that the product was unreasonably dangerous or defective under state product-liability, negligence, or warranty laws.

In short, the decision below authorizes private rights of action that at bottom are based on alleged violations of federal laws requiring information disclosures to federal agencies, rather than on allegations that a product caused harm because it was unreasonably unsafe and defective.

The decision has substantial significance to PLAC, many of whose members are required by federal statutes and regulations to provide to federal regulatory agencies a variety of information about their products and businesses. If not reversed, that holding will have a profoundly deleterious effect not only on manufacturers of medical devices, but on all manufacturers in cases in which a federal preemption defense to such "fraud on the agency" claims is properly advanced. It will effectively require all manufacturers in all federally regulated industries to provide federal agencies not only with the information required by federal statutes and regulations as interpreted by the federal agencies themselves, but also with whatever in-

formation state courts and juries anywhere in the country might decide, under *their* interpretations, the federal agencies should have been provided and would have considered dispositive in deciding what action to take.

Accordingly, PLAC seeks to submit the accompanying brief to inform the Court of the importance of the issues raised by the petition, particularly as they affect manufacturers of products regulated by comprehensive federal safety regulations and statutes with preemption provisions, and the adverse consequences of leaving those issues unreviewed.

For the foregoing reasons, PLAC's motion for leave to file the accompanying brief as *amicus curiae* in support of the petition for a writ of certiorari should be granted.

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June 1999

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IN THE

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v.
PLAINTIFFS' LEGAL COMMITTEE,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Third Circuit

BRIEF FOR PRODUCT LIABILITY ADVISORY COUNCIL, INC., IN SUPPORT OF THE PETITION

INTEREST OF THE AMICUS CURIAE [1]

The interest of the *amicus curiae* is described in the accompanying motion for leave to file this brief.[2]

STATEMENT

Respondent represents thousands of plaintiffs who have sued Petitioner and others for damages and equitable relief

[1] Pursuant to Rule 37.6 of the Rules of this Court, *amicus curiae* states that no counsel for a party has authored this brief in whole or in part and that no person or entity other than *amicus curiae*, its members, or its counsel, has made a monetary contribution to the preparation or submission of this brief.

[2] A list of the members of *Amicus Curiae* Product Liability Advisory Council, Inc., is in the attached Appendix.

for injuries allegedly suffered as a result of surgical implantation of certain screws for spinal fixation. The complaints contain multiple counts, one group of which charges Petitioner and medical device manufacturers with having defrauded the Food and Drug Administration ("FDA"). The decision below denominates these as " 'fraud on the FDA' claim[s]." Pet. App. 1a. Count I of the representative complaint addressed in the decision below is explicitly entitled "Fraud (on the FDA)." Pet. App. 8a.

The "fraud on the FDA" count does not allege that the screws were defective or unreasonably dangerous under product liability, negligence, or warranty principles. *See* Pet. App. 8a-9a. Rather, it alleges (a) that, in applying to the FDA in 1985 for clearance to market the devices, Petitioner "intentionally and falsely represented to the FDA" that the devices were "intended for use in appropriate fractures of long bones of both the upper and lower extremity and such other flat bones"; (b) that, in fact, "the . . . device was intended exclusively for use in the spine"; (c) that the FDA "was ignorant of the fact that these devices and device components were intended by [the defendants] to be used as pedicle screw fixation devices"; (d) that the FDA would not have approved the device for marketing had it known Petitioner's actual subjective intent; and (e) that, as a result of that conduct, the plaintiffs represented by Respondent suffered physical harm. Pet. App. 8a-9a.

The application in question was made pursuant to what is commonly called a "section 510(k) notification," which is provided for in the Medical Device Amendments of 1976 ("MDA")[3] and codified at 21 U.S.C. §§ 360c(f)

[3] Pub. L. No. 94-295, 90 Stat. 539 (1976) (codified as amended in scattered sections at 21 U.S.C. §§ 360c *et seq.*).

(1)(A)(i)-(ii) & 360e(b)(1)(B). Under that process the FDA can permit the marketing of medical devices, such as the devices in question, that are "substantially equivalent" to any of the devices marketed before the MDA's effective date and "grandfathered in" by the MDA under 21 U.S.C. §§ 360c(f)(1)(A)(i) & 360e(b)(1)(A).

FDA regulations in effect at the time of the alleged fraud specified the categories of information that a device manufacturer had to provide to the FDA in a section 510(k) notification. *See* 21 C.F.R. § 807.87 (1986). Those regulations did not state that the manufacturer had to notify the FDA of the manufacturer's subjective intent regarding possible post-clearance "off-label" uses to which physicians might put the device. Instead, the regulations required the manufacturer to submit written materials that the manufacturer proposed to use *overtly* to describe for the medical community the intended use of the device—specifically, "[p]roposed labels, labeling, and advertisement sufficient to describe the device, its intended use, and the directions for its use." *Id.*

Nevertheless, the court of appeals held that neither the MDA's express preemption provision, 21 U.S.C. § 360k, nor implied preemption principles preempted a "fraud on the agency" claim alleging that, in connection with the section 510(k) notification, the defendants had deceived the FDA by not telling the agency that they subjectively "intended [the devices] to be used" for spinal fixation, rather than "in appropriate fractures of long bones of both the upper and lower extremity and such other flat bones." Pet. App. 8a-9a. The court of appeals thus held that a state may create and enforce a state common-law standard that makes medical-device manufacturers liable for omitting from their section 510(k) notifications information neither specifically required by FDA regula-

tions nor requested by the FDA. The court further held that causation could be based upon a jury's finding, without any prior ruling or opinion by the FDA, of what the FDA probably would have done had it received that information.

REASONS FOR GRANTING THE WRIT

UNLESS THIS COURT RESOLVES THE CONFLICT IN THE CIRCUITS OVER THE PREEMPTION OF "FRAUD ON THE AGENCY CLAIMS," THE CONFUSION IN THE LOWER COURTS WILL PREVENT THE CONSISTENT APPLICATION, AND UNDERMINE THE PURPOSES, OF A WIDE VARIETY OF FEDERAL STATUTES AND REGULATIONS

As the Petition shows in detail, the circuits are divided, and the lower courts generally are in a state of confusion, over whether various federal laws, including the MDA and its implementing regulations, preempt "fraud on the agency" claims brought under state laws. *See* Petition for Writ of Certiorari at 11-16, *comparing, e.g., Mitchell v. Collagen Corp.*, 126 F.3d 902, 912 (7th Cir. 1997) ("fraud on the FDA" claims preempted by MDA), *cert. denied*, 118 S. Ct. 1300 (1998), *Lewis v. Brunswick Corp.*, 107 F.3d 1494, 1502 (11th Cir. 1997) ("fraud on the Coast Guard" claims preempted by Boat Safety Act), *cert. dismissed*, 118 S. Ct. 1793 (1998), and *Kuiper v. American Cyanamid Co.*, 131 F.3d 656, 666 (7th Cir. 1997) ("fraud on the Environmental Protection Agency" claims preempted by Federal Insecticide, Fungicide, and Rodenticide Act), *cert. denied*, 118 S. Ct. 1839 (1998), *with, e.g., Connelly v. Iolab Corp.*, 927 S.W.2d 848, 855 (Mo. 1996) ("fraud on the FDA" claims not preempted by MDA), *cert. dismissed*, 520 U.S. 1260 (1997), and *Hoelck v. ICI Americas, Inc.*, 584 N.W.2d 52, 61 (Neb. Ct. App.) ("fraud on the Environmental Protection Agency" claims not preempted by Federal Insecticide, Fungicide, and Rodenticide Act), *review denied* (Oct. 28, 1998). *See also Moore v. Brunswick Bowling & Billiards Corp.*, 889 S.W.2d 246 (Tex.) ("fraud on the Coast Guard" claims not preempted by Boat Safety Act), *cert. denied*, 513 U.S. 1057 (1994).

Without guidance from this Court, the purposes and policies of many federal statutes and regulations will be undermined in several important ways:

- Lower courts will apply preemption principles in an inconsistent manner.
- Federal statutes and regulations requiring manufacturers to disclose specified categories of information to federal agencies will be interpreted and applied by state courts and juries in an inconsistent and unpredictable manner.
- Manufacturers governed by those federal statutes and regulations will be confronted with the anomalous result of being left alone by the federal agency charged with promulgating and enforcing the disclosure requirements, yet subjected to liability, including liability for massive punitive damages, based upon varying interpretations and applications of those federal requirements by state courts and juries.
- Manufacturers will have little choice other than to inundate federal agencies with information and materials not actually required or wanted by the agencies, but that a state court or jury otherwise might conclude should have been provided to the agency.
- And manufacturers who state courts and juries decide should have disclosed different or additional information to federal agencies may be penalized by massive damages awards that result in increased consumer prices for, and reduced availability of, many beneficial products.

A. The Decision Below Undermines Congress' Intent Not to Create a Private Right of Action for Violations of FDA Regulations

Judge Cowen's dissenting opinion below described some of the harmful effects of the majority's decision in the FDA context as follows:

> It is hard to see why that is not in effect creating a private right of action for a violation of the FDA regulation, and it is difficult to reconcile that conclusion with a point the majority itself made in footnote 8: "controlling precedent bars recognition of a private cause of action under the FDCA, the MDA, or their implementing regulations." Given the demanding detail of the regulatory process, and the wide variety of violations ranging from the innocuous to the serious, recognizing a state cause of action for violations of FDA regulations will greatly distort the penalty scheme established by the statute. The penalties attached to a violation of the FDA's regulations will often be substantially increased, and enforcement of violations will no longer be controlled by the FDA's prosecutorial discretion.

Pet. App. 28a (Cowen, J., dissenting). The majority did not disagree with that description of several ways in which judicial recognition of a state cause of action for violations of FDA regulations undermines federal purposes and policies. Nor did the majority disagree that the effect of recognizing a "fraud on the FDA" claim is to create a private right of action for a violation of the FDA section 510(k) notification regulation. Instead, the majority simply declared, "Nor do we hold, as suggested by the dissent, that any of the plaintiffs have stated a claim under the FDA's regulations," *id.* at 25a n.8, and "[i]t is, indeed, well established that Congress has not created an express or implied private cause of action for violations of the FDCA or the MDA," *id.* at 13a.

But regardless of whether the "fraud on the FDA" claim was *formally* pled as "a claim under the FDA's regulations," the dissent was undeniably correct in observing that recognition of such claims *in effect* creates a private right of action for a violation of the FDA regulation. Specifically, the majority's decision permits each individual state to add a completely new private right of action to the pre-existing arsenal of (i) claims of defective design, manufacture, and warning under product-liability and negligence laws, (ii) claims alleging that fraudulent statements were made to physicians or patients, and (iii) claims based on express or implied warranties.

Thus, the decision permitting "fraud on the agency claims" does *not* merely preserve against preemption claims that would have existed in the absence of federal statutes and their implementing regulations. Like decisions by other lower courts holding "fraud on the agency" claims not preempted by other federal statutes and regulations, the decision below cannot be reconciled—other than on the most formalistic, blinkered basis—with its acknowledgment that "controlling precedent bars recognition of a private cause of action under the [federal statutes] or their implementing regulations." *Id.* at 25a n.8.

This is made even clearer by a fuller description of what the representative "fraud on the FDA claim" is *not*, and how it differs from other counts in the complaints:

- The "fraud on the FDA" claim is *not* that the device in issue was defective or unreasonably dangerous in its design, manufacture, or warnings under any state's product-liability or negligence law.
- It is *not* that the defendants made any false or misleading statement to any physician or patient. *See id.* at 26a (Cowen, J., dissenting).

- It is *not* that the device failed to meet the MDA's requirement of being "substantially equivalent to" the predicate devices on which Petitioner based the application. *Id.* at 25a-26a.
- It is *not* that the device was less safe than the predicate devices. *Cf. id.*
- It is *not* that the device was less fit for use for spinal fixation than were the predicate devices. *Cf. id.*
- And it is *not* that the "[p]roposed labels, labeling, and advertisement sufficient to describe the device, its intended use, and the directions for its use" submitted to the FDA pursuant to 21 C.F.R. § 807.87 differed from the labels, labeling, and advertisements that the defendants in fact intended to and did use after FDA approval. *Cf. id.*

Instead, the "fraud on the FDA" claim is solely that, in seeking clearance to market the device for "on-label" long-bone use, the defendants' subjective intent was to market it for "off-label" spinal use; that the FDA's regulations required disclosure of the subjective intent; that the defendants failed to disclose to the FDA that subjective intent; and that the plaintiffs were injured as a result of the nondisclosure. But if Congress had not created the FDA, and if the FDA had not promulgated its regulation requiring manufacturers to submit "[p]roposed labels, labeling, and advertisement sufficient to describe the device, its intended use, and the directions for its use," it would have been impossible for plaintiffs to have alleged that "fraud on the FDA" claim.

Accordingly, the majority below was incorrect in asserting that "it is clear that plaintiffs' 'fraud on the FDA' claims are based on state rather than federal law." Pet. App. 9a. Those claims could not have been made in the absence of, and therefore are based upon, the MDA and its implementing regulations.

B. Unless Resolved by This Court, the Conflict and Confusion in the Lower Courts Will Foster Uncertainty, Inefficiency, and Forum Shopping, and Will Undermine the Policies and Purposes of Many Federal Agencies

The range of adverse consequences generated by recognition of "fraud on the agency" claims is even greater than described by the dissent below. It is best appreciated by first observing that, to prevail on the representative claim addressed by the court below, plaintiffs must prove at least the following:

- The FDA required manufacturers not only to submit "[p]roposed labels, labeling, and advertisement sufficient to describe the device, its intended use, and the directions for its use," but to disclose to the FDA all "off-label" uses to which the manufacturer subjectively hoped physicians would put its devices.
- The manufacturer in fact defrauded the FDA by concealing its subjective intent.
- The FDA had no knowledge of the subjective intent from any other source.
- Had it known of the subjective intent, the FDA would not have cleared the device for marketing for the intended use objectively stated on the labels, labeling, and advertisements that were submitted pre-clearance and used post-clearance.

Plaintiffs' efforts to prove these elements in "fraud on the FDA claims," and other plaintiffs' efforts to prove similar elements in "fraud on the agency claims" based on other federal statutes and regulations, undermine federal purposes and policies in important ways. First, under the decision below, regulated companies must provide to federal agencies not only what the agencies themselves specifically say they want and consider material to safety determinations, but whatever the most extreme state court

or jury concludes should have been disclosed to the federal agency. This could include information that the agency did not intend to require and does not want.

The resulting state-imposed increase in the federal regulatory burden on the regulated companies, and the attendant state-imposed increased burden on federal agencies, would be contrary to federal policies and purposes. Indeed, even if the state laws as thus applied could fairly be said to promote a federal purpose of reducing the risk that defective products will be marketed, it still would conflict with the *method* chosen by Congress and the agency to reduce that risk. *Cf. International Paper Co. v. Ouellette*, 479 U.S. 481, 494 (1987) ("[I]t is not enough to say that the ultimate goal of both federal and state law is [the same]. A state law also is pre-empted if it interferes with the methods by which the federal statute was designed to reach this goal.").

In this case, for example, the FDA regulation in effect when the defendants submitted and obtained approval of their section 510(k) application did not specifically require disclosure of their subjective intent as to how the device might be used off-label by physicians. The representative complaint did not even allege that the FDA had ever stated that it intended or wanted its regulation to require statements of subjective purposes beyond those reflected in the manufacturers' written labeling and advertising. Nevertheless, the decision below permits plaintiffs to ask courts and juries in each state to interpret the regulation to require such disclosures.

The representative complaint also did not allege that the FDA had required manufacturers of the predicate devices to which the devices in issue were "substantially equivalent" to include labeling or advertising about "off-label" uses in spinal surgery. Thus, by subjecting manu-

facturers of new, but substantially equivalent, devices to the threat of massive fraud claims for failing to disclose a subjective intent that their devices be used exactly as the predicate devices were being used, the decision below interferes with section 510(k)'s purpose of fostering competition with "grandfathered" devices that were already on the market when the MDA took effect in 1976 and continued to be marketed thereafter. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 478 (1996); App. 3a.

Second, as a result of the decision below, federal agencies will be burdened by plaintiffs' need, in a wide variety of "fraud on the agency" cases, to prove (i) that the federal agency intended its regulations to mean what the plaintiffs contend they mean, (ii) that the agency relied on the allegedly fraudulent statement, and (iii) that the agency would have taken some different action with respect to the device in question had it received the information the plaintiffs claim it should have received. Likewise, the agencies will be burdened by defendants' attempts in such cases to show (iv) that the agency did not intend to require the information that plaintiffs contend was fraudulently withheld, (v) that, whatever the agency's intent, the agency did not consider the information material to safety determinations, and (vi) that the agency would not have taken any different action had it received the information the plaintiffs claim it should have received. Those burdens will include, in numerous private lawsuits, requests under the Freedom of Information Act, 5 U.S.C. §§ 552, *et seq.*; petitions by plaintiffs asking the agencies to make findings that manufacturers failed to comply with the agencies' disclosure requirements, *see, e.g.*, Letter from Jeffrey L. Fazio to Enid Rubenstein, Office of Chief Counsel, National Highway Traffic Safety Administration, September 19, 1997; National Highway Traffic Safety Administration Special Order In Re PE85-05, PE87-

028, P85-24, September 23, 1997; and requests, by plaintiffs and defendants, for advisory opinions regarding agencies' interpretations of their regulations, *see, e.g., Montag v. Honda Motor Co.*, 75 F.3d 1414, 1418 (10th Cir.), *cert. denied*, 519 U.S. 814 (1996); 10 C.F.R. § 1.23(c) (1998) (providing for interpretive opinions by Office of the General Counsel, Nuclear Regulatory Commission); 21 C.F.R. § 10.85 (providing for advisory opinions by FDA Commissioner); 49 C.F.R. § 501.8 (d)(5) (1997) (providing for interpretive opinions by Chief Counsel, National Highway Traffic Safety Administration).

In particular, defendants will want to obtain from the agency as much information as possible showing that the agency's approval of the application would not have been affected by disclosure of the information that the plaintiffs claim should have been disclosed to it. In this case, for example, the defendants would want to obtain from the agency all agency documents showing at least the following:

- Agency officials understood, from their review of the defendants' first two section 510(k) notifications, which explicitly sought clearance to market the devices for use for spinal fixation, that the defendants hoped that physicians would use the devices "off-label" in that manner, even though the devices would be labeled and advertised solely for long-bone use.
- The predicate devices on which the section 510(k) notification was based had been used "off-label" for spinal fixation, and agency officials knew it.

These many and varied types of information requests by private plaintiffs and defendants impose on the agency the burden of either responding to the requests or refusing

to produce the information and then defending against litigated efforts to compel production.

Third, to the extent that a federal agency succeeds in protecting such information from disclosure—for example, by invoking limits or exemptions under the Freedom of Information Act—litigants in "fraud on the agency" litigation will be prevented from presenting to courts and juries crucial evidence of what the agency intended its regulation to mean, what information the agency considered material, whether the agency relied on the defendants' allegedly false statements, whether the agency knew about the allegedly withheld information from any other source, and whether the agency would have taken any different action absent the alleged fraud. Courts and juries thus will largely have to speculate about the most central elements of "fraud on the agency" claims.

In speculating what action the agency would have taken and why it would have taken it had the agency been provided with the information, the state court or jury may miss the mark completely and reach a conclusion flatly contrary to the one the agency would have reached in furtherance of federal purposes and policies. Here, for example, although plaintiffs filed with the FDA comments alleging the same fraud alleged in the representative complaint addressed in the decision below, the FDA later "granted permission for the bone screws at issue to be labeled for use in spinal fixation." Petition at 17 n.7, citing *In re Orthopedic Bone Screw Prods. Liab. Litig.*, 1995 WL 764580, at *5-*6 (E.D. Pa. Dec. 14, 1995); 63 Fed. Reg. 40025 (1998).

These dangers to federal purposes and policies are substantial, and the uncertainties legion. Here, for example, the decision below emphasizes that the representative complaint alleges that the defendants subjectively in-

tended the device in question to be "*exclusively* for use in the spine" when they filed their section 510(k) notification. App. at 8a (emphasis added). But could a "fraud on the agency" claim likewise proceed if the defendants secretly hoped that 90%, rather than 100%, of post-clearance sales would be for "off-label" use in spinal surgery? 50%? 10%? Would it make any difference if the defendants hoped that the "off-label" use would be minimal at first, but build over a period of several years? Would it make any difference if, when the defendants filed their section 510(k) notification, they hoped that "off-label" uses would occur post-clearance, but they changed their minds before clearance was granted? If they changed their minds the day after clearance was granted? Would federal policies and purposes be rationally served by allowing "fraud on the agency" claims if the subjective intent was formed one week before clearance was granted, but not if the subjective intent was formed one week after clearance was granted, especially where the claim is *not* that the device was defective or unreasonably dangerous?

As for the subjective intent itself, which of the manufacturer's officers, directors, and employees' subjective intent must be disclosed under this state-law interpretation of the federal regulation? For example, which corporate employee's subjective hope that the devices will be used "off-label" for spinal fixation is the subjective intent that matters for "fraud on the agency" claims, especially when the objective labeling and advertising used by the manufacturer properly identify long-bone use as the intended use? What if the chief financial officer harbors that subjective intent, but the chief executive officer does not? What if neither of them harbors that intent, but the marketing director does?

All of these are questions that the federal agency charged by Congress with promulgating and enforcing the regulations should answer. The agency knows what information it needs and wants, and for what purposes. The agency knows what information is important enough to warrant enforcement proceedings when that information is withheld or misrepresented. The agency knows what balance it wishes to strike between ensuring informed decision-making and imposing such massive penalties that competition is impaired, the public is deprived of certain products, the prices of medical devices unduly increase, or the regulated entities inundate the agency with unwanted information in order to avoid such penalties in the future.

Here, in particular, Congress recognized as much by enacting as part of the MDA a broad preemption provision that prohibits the states from establishing

> any requirement (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k. The "fraud on the FDA" claim runs afoul of that express preemption provision, and it also violates conflict-preemption principles in two separate respects.

First, because the FDA's regulations required the section 510(k) notification to include only "[p]roposed labels, labeling, and advertisement sufficient to describe the device, its intended use, and the directions for its use," not a statement of the manufacturer's subjective intent regarding hopes for post-clearance "off-label" uses, the "fraud on the FDA" claim requires information that is

both "different from" and "in addition to" the federal requirements. Second, state laws requiring payment of damages under a "fraud on the agency" claim that does not compensate plaintiffs for harm caused by a product defect impose a requirement that is "different from" and "in addition to" any enforcement requirement that the FDA might choose to impose. At a minimum, the state actions thus conflict with the *method* chosen by Congress and the agency to balance the need for enforcement of federal information-disclosure requirements and the federal goals of fostering competition with "grandfathered" devices, ensuring the availability of important medical devices, and reducing the prices of those devices.

Also, Congress gave the FDA discretion to decide whether a violation of an FDA regulation is a type that should be penalized in any fashion or, instead, whether the public would be disserved by imposing any penalty at all. *See* 21 U.S.C. §§ 336, 337(a). Therefore, it would undermine federal purposes and policies if, as here, the agency determined that no penalty should be imposed for a particular failure to disclose, but private plaintiffs in every state could bring multiple lawsuits based solely on the same nondisclosure and recover millions of dollars in compensatory and punitive damages.

Nor can it be argued that Congress intended to permit the individual states to undermine federal policies and purposes in these numerous ways in order to enable states to compel manufacturers to compensate consumers injured by defective and unreasonably dangerous products. Preemption of "fraud on the agency" claims in no way precludes *any* claim alleging strict product liability, negligence, or breach of warranty for *any* injury caused by *any* allegedly defective or unreasonably dangerous product. Certainly, unlike the manufacturer in *Medtronic*, Petitioner here did not argue that "Congress effectively precluded state courts from affording state consumers any protection from injuries resulting from a defective medical device." *Medtronic*, 518 U.S. at 487.

Accordingly, unlike the preemption of defect-based claims in *Medtronic*, preemption of "fraud on the agency" claims would not have "the perverse effect of granting complete immunity from design defect liability to an entire industry." *Id.* Instead, a failure to hold such claims either expressly or impliedly preempted would have the perverse effect of subjecting manufacturers to massive liability under claims alleging no defect at all. If a device is not defective, so that the plaintiff would recover nothing absent the separate "fraud on the agency" claim, any physical harm the plaintiff may have incurred is causally related to the alleged fraud only in a formal "but for" sense, in the same manner that a pedestrian's injury when struck by a non-negligent driver with an expired license is caused by the violation of the law requiring a valid license.

"Fraud on the agency" claims differ dramatically from product-defect claims in another major respect. When considering whether Congress intended to preempt state laws authorizing damages awards based on alleged product defects, it sometimes can be said that Congress intended the agency's product design or performance requirements to set a "floor," not a "ceiling," on what constitutes an unreasonably unsafe product. Where applicable, that anti-preemption argument can make sense because Congress reasonably could have decided to allow the individual states to decide the levels of product risks to which they are willing to have their citizens exposed. That rationale could not, however, justify a decision not to preempt "fraud on the agency" claims that are over and above any defect claim. "Fraud on the agency" claims go

only to what information the federal agency itself wants to consider and for what purposes, and the states have no basis for substituting their own judgments for those of the agency by forcing manufacturers to provide the agency with additional information or to penalize manufacturers when nondisclosures occur.

This Court repeatedly has emphasized that "[t]he purpose of Congress is the ultimate touchstone" in determining whether preemption precludes the states from using state law to prosecute alleged violations of federal statutes and regulations. *Medtronic*, 518 U.S. at 485. Here, as in several other federal statutes, Congress enacted a broad preemption provision. It should not be read in a way that assigns to Congress an intent to do the absurd. It is all but inconceivable that Congress would have intended to allow individual states to enact statutes requiring manufacturers to disclose to federal agencies specific information that the agencies had not specified in their own disclosure requirements. It is almost as implausible that Congress would have intended to allow individual states to enact statutes imposing multi-million-dollar civil penalties on manufacturers for failing to disclose to the federal agencies specific information that the agencies had specified in their own disclosure requirements. Any such scheme would give to every state the power to override the agency's determination as to whether the failure was significant enough, or sufficiently related to the determination of product safety, to make any penalty at all desirable and, if so, the appropriate size of the penalty. In addition, since "fraud on the agency" claims do not rest on proof of a defective or unreasonably dangerous design, everyone injured in connection with a reasonably safe product could sue, collectively drive the defendant into bankruptcy, impair the competition that the federal law—here, the section 510(k) process—was

intended to foster, and increase the prices of beneficial products needed or desired by consumers.

The fact that the states may choose to impose these penalties through common-law standards, rather than through statutory standards, makes the undermining of federal purposes and policies no less substantial. *See, e.g., Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 386 (1992) (rejecting argument that Federal Aviation Act preempts "only state laws specifically addressed to the airline industry" and not "laws of general applicability" because that interpretation would create an "utterly irrational loophole"). The state standards still conflict with federal law, and they still are preempted.

CONCLUSION

The petition for a writ of certiorari should be granted.

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APPENDIX

APPENDIX

PRODUCT LIABILITY ADVISORY COUNCIL, INC.
CORPORATE MEMBERS

3M
Allegiance Healthcare Corporation
Aluminum Company of America
American Home Products Corporation
American Medical Systems, Inc.
American Suzuki Motor Corporation
Andersen Corporation
Anheuser-Busch Companies, Inc.
Appleton Papers, Inc.
Atlantic Richfield Company
BASF Corporation
Baxter International, Inc.
Bayer Corporation
Becton-Dickinson & Company
BIC Corporation
Black & Decker (U.S.) Inc.
BMW of North America, Inc.
Boeing Company, The
Bombardier Inc., Recreational Products
Bridgestone/Firestone, Inc.
Briggs & Stratton
Brown-Forman Corporation
Budd Company, The
C. R. Bard, Inc.
Caterpillar, Inc.
Celanese Ltd.
CLARK Material Handling Company
Coleman Company, Inc., The
Continental General Tire, Inc.
Coors Brewing Company
Corning Incorporated
DaimlerChrysler Corporation
Dana Corporation
Deere & Company
Digital Equipment Corporation
Dow Chemical Company, The
E. & J. Gallo Winery
Eaton Corporation
Eli Lilly and Company
Emerson Electric Co.
Estee Lauder Companies
Exxon Corporation, U.S.A.
FMC Corporation
Ford Motor Company
Fortune Brands, Inc.
Freightliner Corporation
Gates Corporation, The; Stant Corporation
General Electric Company
General Motors Corporation
Georgia-Pacific Corporation
Glaxo Wellcome Inc.
Goodyear Tire & Rubber Company, The
Great Dane Limited Partnership
Guidant Corporation
Harley-Davidson Motor Company
Harnischfeger Industries Inc.
Heil Company, The
Hoechst Marion Roussel, Inc.
Honda North America, Inc.
Hyundai Motor America
International Paper Company
Isuzu Motors America, Inc.
Johnson & Johnson
Johnson Controls, Inc.
Joseph E. Seagram & Sons, Inc.
Kawasaki Motors Corp., U.S.A.
Kolcraft Enterprises, Inc.
Kraft Foods, Inc.
Loewen Group International, Inc.
Lucas Variety

Lucent Technologies Inc.
Mack Trucks, Inc.
Mazda (North America), Inc.
Medtronic, Inc.
Melroe Company
Mercedes-Benz of North America, Inc.
Michelin North America, Inc.
Miller Brewing Company
Mitsubishi Motors R. & D. of America, Inc.
Motor Coach Industries International, Inc.
Navistar International Transportation Corp.
Nissan North America, Inc.
O. F. Mossberg & Sons, Inc.
Otis Elevator Co.
PACCAR Inc
Panasonic Company
Pentair, Inc.
Pfizer Inc
Philip Morris Companies, Inc.
Porsche Cars North America, Inc.
Procter & Gamble Co., The
Raymond Corporation, The
Raytheon Aircraft Company
Rheem Manufacturing
RJ Reynolds Tobacco Company
Rover Group, Ltd.
Schindler Elevator Corp.
SCM Group USA, Inc.
Sears, Roebuck and Company
Shell Oil Company
Siemens Corporation
Smith & Nephew, Inc.
SmithKline Beecham Corporation
Snap-on Incorporated
Sofamor Danek Group, Inc.
Solutia Inc.
Sturm, Ruger & Co., Inc.
Subaru of America
Taylor Wharton Gas Equipment, A Division of Harsco
Tenneco Automotive
Terex Corporation
Textron Inc.
Thomas Built Buses, Inc.
Toro Company, The
Toshiba America Incorporated
Toyota Motor Sales, USA, Inc.
TRW Inc.
UST (U.S. Tobacco)
Volkswagen of America, Inc.
Volvo Cars of North America, Inc.
Vulcan Materials Company
Whirlpool Corporation
Yamaha Motor Corporation, U.S.A.

(5)

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JUN 2 1999

No. 98-1768

IN THE
Supreme Court of the United States

THE BUCKMAN COMPANY,
Petitioner,

v.

PLAINTIFFS' LEGAL COMMITTEE,
Respondent.

On Petition For Writ Of Certiorari To The United States Court Of Appeals For The Third Circuit

MOTION OF DANEK MEDICAL, INC. FOR LEAVE TO FILE BRIEF AS *AMICUS CURIAE* AND BRIEF AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

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4788

IN THE

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THE BUCKMAN COMPANY,

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MOTION OF DANEK MEDICAL, INC. FOR LEAVE TO FILE BRIEF AS *AMICUS CURIAE* SUPPORTING PETITIONER

Pursuant to Rule 37.2 of the Rules of this Court, Danek Medical, Inc. ("Danek") requests leave to file the accompanying brief as *amicus curiae* in support of the petition for writ of certiorari. Counsel for petitioner consented to the filing of this brief, but counsel for respondent declined.

Danek is the largest supplier of the spinal implant devices in *In re Orthopedic Bone Screw Products Liability Litigation*, MDL-1014, from which this petition for certiorari arises. Danek brought the initial motion to dismiss claims of fraud committed against the Food and Drug Administration ("FDA"), *see* Petitioner's Appendix ("Pet. App.") at 33a-44a. Danek sought to participate in current appeal, but because other claims against it remained, the Court of Appeals held that Danek lacked standing. *See* Pet. App. at 8a n.3. Danek was permitted to participate as *amicus curiae* in the Court of Appeals. *Id.*

Danek should be permitted to participate as *amicus curiae* before this Court because, as a supplier of orthopedic bone screws, it is the target of the full range of the "fraud-on-the-FDA" claims raised in this litigation. Accordingly, Danek has relevant information concerning the broader impact of "fraud-on-the-FDA" claims, both in this litigation and upon FDA administrative determinations generally.

Thus, Danek's participation as *amicus curiae* will assist the Court in understanding the profound impact of allowing common-law reexamination of the basis of any FDA decision—and by extension, any federal administrative action—in private tort actions under state law.

For the foregoing reasons, Danek respectfully requests the Court to grant its motion for leave to file the accompanying brief as *amicus curiae* in support of the petition.

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Dated: June 2, 1999

**Member of the Supreme Court Bar*

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TABLE OF AUTHORITIES

Cases: **Page(s)**

Bailey v. Johnson, 48 F.3d 965 (6th Cir. 1995) 9

Benton v. Kessler, 799 F. Supp. 281 (E.D.N.Y.), *mot. denied*, 506 U.S. 1084 (1992) 6

California v. Federal Energy Regulatory Commission, 495 U.S. 490 (1990) 10

Chicago & North Western Transportation Co. v. Kalo Brick & Tile Co., 450 U.S. 311 (1981) 10

DiCola v. FDA, 77 F.3d 504 (D.C. Cir. 1996) 8

Fiedler v. Clark, 714 F.2d 77 (9th Cir. 1983) 9

In re Grand Jury Proceedings, 861 F. Supp. 386 (D. Md. 1994) 8

Heckler v. Chaney, 470 U.S. 821 (1985) 9

Hughes v. Oklahoma, 441 U.S. 322 (1979) 13

Kuiper v. American Cyanamid Co., 131 F.3d 656, *cert. denied*, 118 S. Ct. 1839 (1998) 14

Lewis v. Brunswick Corp., 107 F.3d 1494 (11th Cir. 1997), *cert. dismissed*, 118 S. Ct. 1793 (1998) 6,14

McDermott v. Wisconsin, 228 U.S. 115 (1913) 6

Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996) 4,9,11 12,13,14

Mitchell v. Collagen Corp., 126 F.3d 902 (7th Cir. 1997), *cert. denied*, 118 S. Ct. 1300 (1998) 14

Mylan Laboratories, Inc. v. Matkari, 7 F.3d 1130 (4th Cir. 1993), *cert. denied*, 510 U.S. 1197 (1994) 9

TABLE OF AUTHORITIES—*(Continued)*

Cases: **Page(s)**

In re Orthopedic Bone Screw Products Liability Litigation, 159 F.3d 817 (3d Cir. 1998) (Pet. App. 1a-32a) 10,11,12,14

In re Orthopedic Bone Screw Products Liability Litigation, MDL-1014, 1997 WL 186325 (E.D. Pa. Apr. 16, 1997) (PTO 861) 3

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In re Orthopedic Bone Screw Products Liability Litigation, MDL-1014, 1996 WL 482977 (E.D. Pa. Aug. 22, 1996) (PTO 477) 3,5

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Pacific Trading Co. v. Wilson & Co., 547 F.2d 367 (7th Cir. 1976) 9

PDK Labs, Inc. v. Friedlander, 103 F.3d 1105 (2d Cir. 1997) 9

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TABLE OF AUTHORITIES—*(Continued)*

Cases: **Page(s)**

United States v. Bhutani, __ F.3d __, 1999 WL 25042 (7th Cir. Apr. 28, 1999) 8

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United States v. Chatterji, 46 F.3d 1336 (4th Cir. 1995) 8

United States v. Garfinkle, 29 F.3d 1253 (8th Cir. 1994) 8

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21 U.S.C. §332 8

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21 U.S.C. §333(b)(2)(B) 8

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21 U.S.C. §334(a)(2)(D) 8

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21 U.S.C. §335a(b) 8

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21 U.S.C. §355(d) 7

21 U.S.C. §355(i) 7

21 U.S.C. §355(k) 7

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21 U.S.C. §360 7

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21 U.S.C. §360e(b) 7

21 U.S.C. §360e(c) 7

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21 U.S.C. §360k 7
21 U.S.C. §360k(a) 2,6,12
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21 C.F.R. §211.182 7
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21 C.F.R. §211.186 7
21 C.F.R. §211.188 7
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21 C.F.R. §821.50 7

21 C.F.R. §821.20 7

21 C.F.R. §820.25 7

21 C.F.R. §860.7 4,7

21 C.F.R. §860.120 4,7

21 C.F.R. §860.123 4,7

21 C.F.R. §860.125 4,7

21 C.F.R. §860.130 4,7

21 C.F.R. §860.132 4,7

21 C.F.R. §860.134 4,7

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S. Rep. No. 33, 94th Cong., 2d Sess. (1976) (reprinted at 1976 U.S.C.C.A.N. 1070) 2

S. Rep. No. 284, 104th Cong., 2d Sess. (1996) 6

S. Rep. No. 468, 101st Cong., 2d Sess. (1990) 6

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63 Fed. Reg. 40025 (FDA Jul. 27, 1998) 3,4,5

TABLE OF AUTHORITIES—*(Continued)*

Cases: **Page(s)**

FDA Disqualified/Restricted Assurances List for Clinical Investigators (last modified Apr. 29, 1999) <http://www.verity.fda.gov> 9

FDA, Office of Regulatory Affairs, Office of Enforcement, Division of Compliance Policy—Debarment List (last modified Sep. 28, 1998) <http://www.fda.gov/ora/compliance_ref/debar/default.htm> 9

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IN THE

Supreme Court of the United States

No. 98-1768

THE BUCKMAN COMPANY,

Petitioner,

v.

PLAINTIFFS' LEGAL COMMITTEE,

Respondent.

On Petition For Writ Of Certiorari To The United States Court Of Appeals For The Third Circuit

BRIEF OF DANEK MEDICAL, INC. AS *AMICUS CURIAE* SUPPORTING PETITIONER

INTEREST OF THE *AMICUS CURIAE*

The interest of Danek Medical, Inc. ("Danek") as *amicus curiae* is described in the preceding motion for leave to file this brief.[1]

SUMMARY OF ARGUMENT

Respondent Plaintiffs' Legal Committee ("PLC") represents hundreds of plaintiffs in personal injury litigation against suppliers of orthopaedic bone screws used in plaintiffs' spines during spinal fusion surgery. "Fraud on the FDA" is one of the PLC's many state-law claims. The PLC asserts that virtually every important FDA decision concerning these screws since 1986 rests upon untrue information provided by the suppliers of these devices or by their agents. This "fraud," the PLC claims, allows state-law juries to treat these FDA regula-

1. No counsel for any party authored any portion of this *amicus curiae* brief, and no one other than Danek made any monetary contribution to the preparation or submission of this brief. Supreme Court Rule 37.6.

tory actions as if they did not exist, and to hold Danek and other defendants liable for supplying products lacking any FDA marketing permission.

Either under the express preemption provision of the Medical Device Amendments ("MDA") to the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. §360k(a), or under principles of implied preemption, this novel claim of "fraud on the FDA" is preempted. Otherwise, a jury in a state-law action could reexamine almost everything the FDA does, and different juries may reach different conclusions regarding the validity of FDA actions. The pervasive interference with FDA actions that "fraud-on-the-FDA" claims entail is exemplified by the breadth of the PLC's charges against Danek in this very litigation.

ARGUMENT

In enacting the MDA in 1976, Congress sought to protect public health by balancing the need for regulation of medical devices with the need for development of new and improved devices without excessive cost or delay.[2] A critical part of that balance—preservation of the FDA's ability to do its job without being second-guessed in state tort litigation—is directly presented to the Court by the certiorari petition filed by the Buckman Company.

2. *See* S. Rep. No. 33, at 7 (1976) ("a balance [should] be struck between the need for continuing research and the need for improved patient protection"), at 13 (intent that "innovation is not stifled" and that " 'quack' devices or devices known to be unsafe or ineffective" not be allowed) (reprinted at 1976 U.S.C.C.A.N. 1076, 1083); H.R. Rep. No. 853, 94th Cong., 2d Sess. at 10 (1976) ("protection against unsafe, unproven, ineffective and experimental medical devices" is "counterbalanced by an equally strong conviction that excessive . . . regulation would stifle progress").

I. "Fraud-on-the-FDA" Claims Expose FDA Decisions To Collateral Attack In State Courts, In Direct And Inherent Conflict With The Regulatory Scheme Enacted by Congress.

A. *The PLC's Claims Seek State Jury Nullification Of Every FDA Decision Regulating Spinal Implants Between 1986 and 1998.*

The PLC has brought "fraud-on-the-FDA" allegations against a wide range of FDA decisions involving every manufacturer of orthopaedic bone screws. *See* Petitioner's Appendix ("Pet. App.") at 43a-44a; *In re Orthopedic Bone Screw Products Liability Litigation*, MDL-1014, 1996 WL 482977, at *2 (E.D. Pa. Aug. 22, 1996) (PTO 477). These claims contest the validity of scores of FDA clearances of spinal implant devices since 1984, as well as the 1995 FDA decision to begin clearing "pedicle screws" as such and the general reclassification of "pedicle screw spinal systems" that the FDA proposed in 1995 and finalized in 1998. *See* 63 Fed. Reg. 40025 (FDA Jul. 27, 1998); 60 Fed. Reg. 51946 (FDA Oct. 4, 1995).[3]

The *John Lee Ramey* complaint, the MDL Court's exemplar of claims against Danek[4] (reproduced in pertinent part as Appendix "A") reveals the scope of the PLC's "fraud-on-the-FDA" claims. It alleges that the initial 1986 FDA clearance of the Danek "Luque II" components used in Mr. Ramey's surgery seven years later in 1993, was fraudulent because Danek supposedly misstated the "intended use" of the screw components. App. "A" at 3a ¶¶90-100. There is no claim that Mr. Ramey, his surgeon, or anyone involved in his treatment knew of or acted in detrimental reliance upon any misstatement. *Id.* at 8a ¶¶126-28.

The *Ramey* complaint further alleges that Danek defrauded the FDA with respect to devices not used in Mr.

3. The FDA's Final Rule was published on July 27, 1998, after oral argument in the Third Circuit. FDA decisions published in the Federal Register are entitled to judicial notice. 44 U.S.C. §1507.

4. *See In re Orthopedic Bone Screw Products Liability Litigation*, MDL-1014, 1997 WL 186325, at *2 n.3 (E.D. Pa. Apr. 16, 1997) (PTO 861).

Ramey's surgery. These allegations likewise involve "intended use," rather than the physical characteristics, medical risks, or medical benefits of any device:

- In 1988-89, Danek allegedly misstated the "intended use" of "sacral" screw components of a device called the "TSRH" system. *Id.* at 6a-7a ¶¶105-110, 114-15.
- In 1990-92, Danek allegedly misstated the "intended use" of "variable angle" screw components of the TSRH system. *Id.* ¶¶111-15.
- In 1991-92, Danek allegedly misstated the "intended use" of the screw components of a device called the "Dyna-Lok" system. *Id.* at 7a-8a ¶¶120-25.

Further allegations of fraud involve the FDA's January 20, 1995 decision to clear TSRH screws specifically for use in the lumbar pedicles of the spine. Although this event occurred after Mr. Ramey's 1993 surgery, the PLC alleges that Danek (aided by other screw suppliers) submitted a false affidavit to prove that there was a pre-Amendments "substantially equivalent" device.[5] App. "A" at 13a-18a ¶¶244-75.

Still more fraud allegations in the *Ramey* complaint involve the FDA's October 4, 1995 proposal to reclassify "pedicle screw spinal systems" generally as safe and effective. The PLC attacks a large "cohort study" that the FDA concluded was "valid scientific evidence" of the safety and effectiveness of bone screws when used for pedicle fixation. *Id.* at 3a-13a ¶¶240-43. *See* 60 Fed. Reg. at 51947, 51950-54.[6]

The PLC's "fraud-on-the-FDA" allegations in this litigation thus are not limited to one device or one supplier. Rather, they attack the FDA's decision to allow marketing of most of the spinal fixation devices that now exist. Each action also seeks to void all the regulatory steps that the FDA has taken

5. The Danek clearances at issue all involve the same "substantial equivalence" procedure that was described by the Court in *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 478-480 (1996).

6. Reclassification is a separate process by which a device can receive a lower device classification if the FDA is presented with "valid scientific evidence" of the device's safety and effectiveness. 21 U.S.C. §360c(e); 21 C.F.R. §§860.7, 860.120-860.134.

since 1995 to address the regulatory status of these devices. There are hundreds of these cases. *Orthopedic Bone Screw*, 1996 WL 482977, at *9. Each is nothing less than an attempt to use state law to nullify ten years of FDA regulatory activity.

The PLC persists even though the FDA examined the same fraud allegations and found them wanting. The FDA's proposal to reclassify spinal implants invited public comments, and the MDL Court allowed the PLC to use MDL discovery in its comments.[7] On March 1, 1996, the PLC filed several hundred pages of comments with the FDA—including the basis for its "fraud-on-the-FDA" claims against Danek.[8]

On July 27, 1998, as part of its Final Rule approving reclassification, the FDA addressed the PLC's fraud claims. It rejected the PLC's allegations that bone screws should be prohibited due to "deception":

> After reviewing all available data and information, . . . FDA does not believe that pedicle screw spinal systems present a substantial deception or an unreasonable and substantial risk of illness or injury. Consequently, FDA does not believe it would be appropriate to ban them.

63 Fed. Reg. at 40035-36 (Item 28). The FDA further determined to retain all existing screw clearances. *Id.* at 40031 (Item 8), 40032-33 (Items 13-16), 40039 (Item 44). In reaching this decision, the FDA reviewed the PLC's fraud allegations involving the 1995 Danek TSRH clearance and the "cohort study" in great detail and rejected the PLC's claims point by point. *Id.* at 40032-33 (Items 13-16) (TSRH clearance); at 40029-30 (Items 2-3) ("cohort study").

7. *See* 60 Fed. Reg. at 51946 (setting public comment period); *In re Orthopedic Bone Screw Products Liability Litigation*, MDL-1014, 1995 WL 764580, at *5 (E.D. Pa. Dec. 14, 1995) (PLC may use confidential MDL documents in FDA public comments) (PTO 179).

8. *See* "Comments by Plaintiffs' Legal Committee in *In re Orthopedic Bone Screw Products Liability Litigation*, MDL Docket 1014, Concerning Proposed Rule Making," FDA Dkt. No. 95N-0176 (filed March 1, 1996).

The scope of the PLC's "fraud-on-the-FDA" allegations in the *Orthopedic Bone Screw* litigation, coupled with the FDA's adverse determination of them, point out the error of the Court of Appeals' reasoning. The PLC's attempt to overturn FDA clearances of every device involved in this litigation demonstrates that "fraud-on-the-FDA" claims do indeed seek to impose a legal requirement—not to sell the same devices that the FDA has cleared to be marketed—that is "different from or in addition to" FDA requirements imposed under the FDCA, *see* 21 U.S.C. §360k(a), and are therefore preempted.

Just as starkly, these claims illuminate how any "fraud-on-the-FDA" claim inherently conflicts with the specific FDA action that the claim seeks to nullify, and is therefore impliedly preempted. *See McDermott v. Wisconsin,* 228 U.S. 115, 132-34 (1913); *Lewis v. Brunswick Corp.,* 107 F.3d 1494, 1502 (11th Cir. 1997), *cert. dismissed,* 118 S. Ct. 1793 (1998). Because litigants in individual state-law cases may not ask lay juries to reexamine complex FDA decisions to allow medical devices and drugs to enter a nationwide market, this Court should grant the petition for certiorari.

B. *The Regulatory Structure Enacted By Congress Precludes The PLC's Attempted Collateral Attack Upon FDA Decisions.*

The vast potential of state-law "fraud-on-the-FDA" claims to disrupt FDA administration of the FDCA is also apparent from the FDA's role in the statutory scheme. The FDCA does not vest the FDA with authority to seek out and investigate drugs or medical devices for possible clearance. *Benton v. Kessler,* 799 F. Supp. 281, 284-85 (E.D.N.Y.), *mot. denied,* 506 U.S. 1084 (1992); *see* S. Rep. No. 468, at 204, 101st Cong., 2d Sess. (1990) (no FDA authority to establish clinical research facilities). Nor does the FDA have authority to evaluate off-label uses on its own volition. *See* S. Rep. No. 284, at 76, 104th Cong., 2d Sess. (1996). Like many administrative bodies, the FDA acts in response to information that the governing statute requires regulated persons, and allows others, to submit to the Agency.

FDCA requirements for submission of information to the FDA are pervasive. Each of the three avenues by which medical devices come onto the market requires evaluation of information submitted by manufacturers, distributors, and their agents.[9] The same is true with the processes for approval of new drugs and biologics.[10] After the FDA has given permission for a product to be marketed, manufacturers and distributors must provide a wide variety of additional information to the FDA, any of which could lead to future FDA action.[11] Every FDA action based upon submitted information is potentially subject to second-guessing and common-law nullification if "fraud-on-the-FDA" claims survive preemption.

Nor does the FDA need common-law assistance because it cannot defend itself from an onslaught of false information.

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9. *See* 21 U.S.C. §360e(c); 21 C.F.R. §814.20 (describing information to be submitted to the FDA in support of pre-market approval application); 21 U.S.C. §360c(e-f); 21 C.F.R. §860.123 (same; reclassification); 21 U.S.C. §§360(k), 360e(b); 21 C.F.R. §§807.87-807.93 (same; pre-market notification).

10. *See* 21 U.S.C. §355(a-d,i); 21 C.F.R. §§312.20-.23, 314.50-.54 (submission requirements for new drugs); 42 U.S.C. §262(a,j); 21 C.F.R. §§601.3, 601.20-601.25 (submission requirements for new biologics).

11. **Devices:** *E.g.,* 21 U.S.C. §§360i (record keeping), 360j(f)(2) (variance from good marketing practices), 360l (post-market surveillance); 360ll, 360nn(a-b,d,f) (electronics inspection/reporting), 360aaa-3 (supplemental application for new use); 21 C.F.R. §§803.1-.56, 804.1-.35 (adverse experience), 806.10, 820.100 (corrections), 807.20-.31 (device/establishment listing), 810.10(d), 810.15-.16 (cease distribution/recall), 820.30 (design/development), 820.70(b) (production/process changes), 820.120 (labeling), 820.181-.186, 821.50 (records), 820.198 (complaints), 821.20-.25 (device tracking), 860.7, 860.120-860.134 (reclassification). **Drugs:** *E.g., 21* U.S.C. §§355(k) (record keeping), 356b (postmarketing study), 356c (discontinuation), 360 (registration/listing), 360b(e)(1)(F) (failure to supplement application); 21 C.F.R. §§201.1-.15, 201.50-.57, 201.60-.63, 211.134(d,e), 314.70 (labeling), 207.20-.37 (establishment/drug listing), 211.180-.196 (record keeping), 211.198 (complaints), 310.303, 314.81, 314.420 (records/reports), 314.54 (indication changes), 314.70-.71 (supplement to approved application), 314.72 (change of ownership), 314.80 (adverse experience). **Biologics:** *E.g.,* 21 C.F.R. §§600.12 (record keeping), 600.14 (errors), 600.21-.22 (inspections), 600.80 (adverse experience), 600.81 (distribution), 601.4 (licenses), 601.12 (changes to approved applications), 601.26 (reclassification), 610.9, 610.11(c) (procedure modifications), 610.60-.64 (labeling).

Quite the contrary, the FDCA provides the FDA with an imposing arsenal of sanctions should it conclude that it has been the victim of fraud. In addition to felony criminal sanctions under 18 U.S.C. §1001, the FDA has numerous administrative sanctions at its disposal:

- injunctions against violations or further marketing, 21 U.S.C. §332;
- enhanced criminal penalties upon proof of "intent to defraud," *id.* §333(a);
- civil fines up to $1,000,000, *id.* §§333(b)(2)(B), 333(f)(1)(A), 335b(a);
- seizure and forfeiture, *id.* §334(a)(2)(D);
- detention without prior notice, *id.* §334(g);
- barring implicated companies or individuals from involvement with further submissions to the FDA, *id.* §335a(a-e);
- denial, suspension, or termination of activities tainted by fraud, *id.* §335a(f-h);
- withdrawal of approval, *id.* §335c;
- warning letters for "minor violation[s]," *id.* §336;
- permanent ban of the product at issue, *id.* §360f; and
- mandatory recall. *Id.* §360h(e).

Nor has the FDA been reluctant to use its powers. Recent case law abounds with examples of prosecutions for making false statements to the FDA.[12] Many FDA enforcement actions are for false or fraudulent submissions. For example, from March 1993 through June 1998, the FDA permanently debarred 47 persons and temporarily debarred 2 others for

12. *E.g., United States v. Bhutani,* __ F.3d __ , 1999 WL 25042 (7th Cir. Apr. 28, 1999); *Takhar v. Kessler,* 76 F.3d 995 (9th Cir. 1996); *United States v. Ballistrea,* 101 F.3d 827 (2d Cir. 1996); *DiCola v. FDA,* 77 F.3d 504 (D.C. Cir. 1996); *United States v. Chatterji,* 46 F.3d 1336 (4th Cir. 1995); *United States v. Garfinkle,* 29 F.3d 1253 (8th Cir. 1994); *United States v. Radix Laboratories, Inc.,* 963 F.2d 1034 (7th Cir. 1992); *see also United States v. C.R. Bard, Inc.,* 848 F. Supp. 287 (D. Mass. 1994); *In re Grand Jury Proceedings,* 861 F. Supp. 386 (D. Md. 1994).

providing false information.[13] The FDA has also disqualified 87 clinical investigators from further participation in clinical trials and has restricted numerous others.[14]

In direct contrast to the FDA's multi-faceted enforcement capabilities, the FDCA provides no enforcement role for would-be "private attorneys general" such as the PLC. The FDCA specifically states:

> Except as provided in subsection (b) of this section [relating to actions by state governments], all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States.

21 U.S.C. §337(a). On the strength of §337(a), this Court in *Medtronic, Inc. v. Lohr,* 518 U.S. 470, 477 (1996), and every Court of Appeals to consider the question, has held that no private rights of action exist under the FDCA.[15]

Congress further manifested its intent that the FDA should control FDCA enforcement by granting prosecutorial discretion to the FDA:

> Nothing in this chapter shall be construed as requiring the [FDA] to report for prosecution. . .minor violations of this chapter whenever [it] believes that the public interest will be adequately served by a suitable written notice or warning.

21 U.S.C. §336. "The Act's enforcement provisions. . .commit complete discretion to [FDA] to decide how and when they should be exercised." *Heckler v. Chaney,* 470 U.S. 821, 835

13. *See FDA, Office of Regulatory Affairs, Office of Enforcement, Division of Compliance Policy—Debarment List* (last modified Sep. 28, 1998) <http://www.fda.gov/ora/compliance_ref/debar/default.htm>.

14. *See FDA Disqualified/Restricted Assurances List for Clinical Investigators* (last modified Apr. 29, 1999) <http://www.verity.fda.gov>.

15. *PDK Labs, Inc. v. Friedlander,* 103 F.3d 1105, 1113 (2d Cir. 1997); *Bailey v. Johnson,* 48 F.3d 965, 968 (6th Cir. 1995); *Mylan Laboratories, Inc. v. Matkari,* 7 F.3d 1130, 1139 (4th Cir. 1993), *cert. denied,* 510 U.S. 1197 (1994); *Rodriguez v. SK&F Co.,* 833 F.2d 8, 9 (1st Cir. 1987); *Fiedler v. Clark,* 714 F.2d 77, 79 (9th Cir. 1983); *Pacific Trading Co. v. Wilson & Co.,* 547 F.2d 367, 370 (7th Cir. 1976).

(1985). As discussed, *supra,* at pp. 4-5, the FDA spent more than two years investigating the PLC's "fraud-on-the-FDA" claims before rejecting them in issuing its 1998 Final Rule.

Ad hoc reexamination of FDA decisions by lay juries in state-law actions around the country is incompatible with the regulatory structure Congress has put in place. The PLC seeks to "use the threat of damages to require [defendants] to do exactly what [the FDA] is empowered to excuse." *Chicago & North Western Transportation Co. v. Kalo Brick & Tile Co.,* 450 U.S. 311, 326 (1981). The PLC wants state-law juries to disagree with the FDA's 1998 rejection of its fraud allegations. The FDCA does not contemplate "a dual system of futile duplication of two authorities over the same subject matter." *California v. Federal Energy Regulatory Commission,* 495 U.S. 490, 502 (1990) (citation and quotation marks omitted). Preemption maintains both the FDA's exclusive enforcement powers and its prosecutorial discretion.

II. Contrary To The Third Circuit, This Court Did Not Hold In Medtronic That "Fraud-on-the-FDA" Claims Were Not Preempted.

The Third Circuit did not profess to recognize a private FDCA action for "fraud on the FDA." *See* Pet. App. at 13a. Rather, without citation, the Court of Appeals held, "[w]e see no inconsistency between the FDA having the exclusive prerogative of bringing actions to enforce the FDCA" and private plaintiffs "bring[ing] common-law fraudulent misrepresentation claims." *Id.* at 18a. The error in this reasoning is that "fraud on the FDA" is not a traditional common-law fraud claim, but instead is fundamentally different.

Traditional fraud claims are predicated upon a defendant, directly or indirectly, passing false information to a plaintiff, who detrimentally relies upon that information.[16] The PLC

16. *See* Restatement (Third) of Torts, Products Liability §9 & comment c (1997) (misrepresentation must be "in connection with the sale of a product," and reliance is required); Restatement (Second) of Torts §402B & comment j (1965) (misrepresentation must be "to the public," and reliance is required); Restatement (Second) of Torts §310 & comment c (1965) (must be reliance upon the misrepresentation, such as a third person's mistaken belief as to safety); Restatement (Second) of Torts §§537, 548 (1976) (must be reliance upon the misrepresentation).

does not claim that any plaintiff, treating surgeon, or anyone outside the FDA[17] relied upon, knew of, or even had reason to know of, allegedly false statements of "intended use" made to the FDA years before their surgeries.

Nor are tort actions based upon procedural irregularities. "Negligence *per se*" involves violation of substantive safety standards.[18] Administrative guidelines, such as the content of administrative submissions, do not give rise to tort claims for their violation.[19] Procedural attacks upon federal administrative decisions are federal questions governed by the Administrative Procedure Act ("APA").[20] "Fraud on the FDA" is not a "field which the States have traditionally occupied." *Medtronic,* 518 U.S. at 485 (citation and quotation marks omitted).

The PLC's "fraud-on-the-FDA" claims are dependent, not upon traditional tort reliance, but rather upon the claimed invalidity of FDA actions. The Third Circuit recognized this fact, but failed to appreciate its significance. *See* Pet. App. at 21a ("without Buckman's fraudulent representation, the FDA would not have given AcroMed a §510(k) clearance and that, absent a §510(k) clearance, AcroMed would not have access to the market"). Thus, the PLC's "fraud-on-the-FDA" claims

17. Federal law exempts FDA employees from civil discovery regarding their performance of FDA duties. 21 C.F.R. §20.1(a-b). Thus the most crucial evidence of the actual effect of supposed "fraud" upon internal FDA decision-making is unavailable to civil litigants.

18. *See* Restatement (Third) of Torts, Products Liability §4, comment a (1997) (violation claims limited to "final governmental edicts and directives . . . that establish binding safety standards").

19. *See* Restatement (Second) of Torts §288(a) (1965) (negligence *per se* not applicable to enactments that "protect the interests of the state or any subdivision of it as such").

20. *See, e.g.,* 5 U.S.C. §702; 28 U.S.C. §1331. Indeed, the PLC is simultaneously prosecuting an APA action against the 1998 FDA Final Rule. *See Cosom, et al. v. United States Food & Drug Administration,* C.A. No. 98-CIV-4643 (E.D. Pa.).

empower common-law juries to nullify administrative actions taken by the FDA—by declaring the "absence" of those FDA actions.

The PLC does not seek repetition of any FDA proceeding with "truthful" information. Rather, it wants juries to void FDA actions retroactively and to award damages. The conflict between this "tort" and a specific FDA requirement (here, clearance for marketing) imposed upon a specific device is total, because a jury is to be asked to treat a standing FDA decision as invalid. The conflict is also inherent, because unless the jury nullifies the FDA decision, the PLC's claim cannot succeed.

Nor was the Third Circuit correct to rely upon the rationale of the *Medtronic* plurality that lack of private FDCA rights of action was "evidence of an intent *not* to preempt common law liability." Pet. App. at 15a (citing *Medtronic*, 518 U.S. at 487) (emphasis original). *Medtronic* did not involve any claim having nullification of an FDA action as an essential element. The *Medtronic* plurality rejected an argument that §360k(a) preempted all state-law claims—a discussion that is inapposite, since the PLC may pursue (and is pursuing) unpreempted claims such as design and warning defects. No member of this Court held in *Medtronic* that, no matter how great the conflict with the FDA's interpretation of its requirements, no state-law claim could be preempted.

"Fraud on the FDA" is not analogous to any claim at issue in *Medtronic*, and the Court of Appeals' decision would avoid even preemption that is appropriate under *Medtronic*. No member of this Court disagreed with Justice Breyer that "a federal MDA regulation requir[ing] a 2-inch wire" would preempt a state tort claim "that use of a more than 1-inch wire is negligent." 518 U.S. at 504 (Breyer, J., concurring). But the Third Circuit would require only a claim that the "2-inch" regulation was the product of fraud upon the FDA to avoid preemption.

In particular, "fraud on the FDA" is the polar opposite of the "identity of requirements" claim that *Medtronic* unanimously held was not preempted.[21] In *Medtronic* the only allegation was that the defendant "violated FDA regulations." 518 U.S. at 495. The state-law duties in *Medtronic* thus "paralleI[ed] federal requirements." *Id.* Here, "fraud on the FDA" requires state-law juries to set aside what the PLC claims are fraudulently obtained FDA clearances—despite those fraud allegations having been investigated by the FDA and determined to be without merit. A greater divergence between the requirements of federal and state law would be difficult to envision.[22]

Danek is a national seller of medical devices, and the *Orthopedic Bone Screw* litigation is equally nationwide in scope. After the Court of Appeals' decision, however, Danek faces the likelihood that the validity *vel non* of the FDA clearances for its devices—and thus Danek's ability to market its products at all—may vary from state to state, or even within a state, depending on conflicting verdicts of lay juries.

"Fraud-on-the-FDA" claims also have practical ramifications. *First*, while the FDA only requires submission of one "intended use" to support device clearance, *see* 21 C.F.R. §807.92(a)(5), the PLC's claim effectively demands FDA submission of full information about every possible "intended use"—forcing the FDA to wade through information that the Agency neither wants nor needs.

Second, suppliers of medical devices and drugs could not inform physicians of medical advances using their products, as permitted by the FDCA, 21 U.S.C. §360aaa, without fear of exposing their FDA-recognized "intended uses" to state-law challenge as "fraudulent."

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21. 518 U.S. at 494–97 (opinion of the Court), 513 (O'Connor, J. concurring, joined by the Chief Justice and Scalia and Thomas, JJ.)).

22. The PLC's feigned allegiance to FDCA procedures cannot support its attempt to overturn the substantive FDA decisions resulting from those procedures. Courts are "not bound by the name, description or characterization" of state law, "but will determine for [themselves] the practical impact of the law." *Hughes v. Oklahoma*, 441 U.S. 322, 336 (1979) (citation and quotation marks omitted).

Third, because fraud, rather than a defective product, is the basis of the claim, "fraud on the FDA" could be asserted by competing device and drug companies to interfere with their competitors' products. *Cf. Medtronic,* 518 U.S. at 494 & n.14 (discussing "procompetition" purpose of the FDA clearance process at issue in this litigation).

Collateral attacks upon FDA decisions threaten suppliers of medical devices and drugs with liability, not for defective products, but for marketing their products in reliance upon FDA decisions that any state-law jury may later decide should be retroactively annulled. This potential for divergent results is only aggravated by the conspicuous split among the circuits that the decision here opened.[23] Because subjecting medical device and drug manufacturers to inconsistent state-law decisions on the basic issue of whether their products are legally marketed was not what Congress intended when it enacted the FDCA, this Court should grant the petition for certiorari.

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23. *See* Pet. App. at 17a n.5 (acknowledging disagreement with *Mitchell v. Collagen Corp.*, 126 F.3d 902 (7th Cir. 1997), *cert. denied,* 118 S. Ct. 1300 (1998)). Other Court of Appeals decisions finding claims of fraud on an administrative agency preempted include: *Kuiper v. American Cyanamid Co.*, 131 F.3d 656, 666 (7th Cir. 1997), *cert. denied,* 118 S. Ct. 1839 (1998); *Lewis,* 107 F.3d at 1502; *Talbott v. C.R. Bard, Inc.*, 63 F.3d 25, 28 (1st Cir. 1995), *cert. dismissed,* 517 U.S. 1230 (1996); *Welchert v. American Cyanamid, Inc.*, 59 F.3d 69, 73 (8th Cir. 1995); *Reeves v. AcroMed Corp.*, 44 F.3d 300, 306 (5th Cir.), *cert. denied,* 515 U.S. 1104 (1995); *Worm v. American Cyanamid Co.*, 5 F.3d 744, 748 (4th Cir. 1993).

CONCLUSION

Because of the profound impact of allowing "fraud-on-the-FDA" claims, not only upon FDA administration and enforcement of the FDCA, but also upon the integrity of federal administrative actions generally, the Court should grant the petition for writ of certiorari.

Respectfully submitted,

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Dated: June 2, 1999

**Member of the Supreme Court Bar*

APPENDIX

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

John Lee Ramey and Candice Ramey, Plainfiffs, v. Danek Medical, Inc.; Sofamor-Danek Group, Inc.; Warsaw Orthopedic, Inc.; Eduardo Luque; Charles E. Johnston, II; Richard Ashman, Ph.D.; Gary Lowery; George Rapp; Ensor Transfeldt; John A. Herring; Thomas Whitecloud, III; Thomas A. Zdeblick; Youngwood Medical Specialties, Inc., f/k/a/ National Medical Specialty, Inc., f/k/a/ Stuart Medical Specialty, Inc.; Stuart Medical, Inc., f/k/a/ Stuart Drug and Surgical Supply, Inc.; Texas Scottish Rite Hospital for Crippled Children; American Academy of Orthopaedic Surgeons; North American Spine Society; Scoliosis Research Society; Spinal Science Advancement Foundation; Acromed Corporation, Charter No. 614043; Acromed Corp. (Now Acromed Corporation, Charter No. 614043); Acromed Corporation, Charter No. 816942; Acromed, Inc., Charter No. 811415; Acromed Incorporated (Now Acromed Inc., Charter No. 811415); Acromed Incorporated, Charter No. 816943; Acromed Holding Corporation, Charter No. 811416; Acromed Corporation (Now Acromed Holding Corporation, Charter No. 811416); Ace Medical Company; Advanced Spine Fixation Systems, Inc.; Cross Medical Products, Inc.; DePuy-Motech, Inc.; Smith & Nephew Richards, Inc.; Sofamor, S.N.C.; Sofamor, Inc.; Synthes (U. S.A.); Synthes, Inc.; Synthes North America, Inc.; Synthes; A.G.; Zimmer, Inc., Defendants.	MDL 1014 CIV. NO. 96-422 D. MD. CIV. NO. 95 CV 3194 JURY TRIAL DEMANDED

FIRST AMENDED COMPLAINT

* * *

3. On March 1, 1993, Dr. A.H. Dudley performed surgery on Plaintiff at Children's Hospital in Baltimore, Maryland and implanted a Danek pedicle screw fixation device known as the Luque device in Plaintiffs spine.

* * *

Count I: Fraud (on the FDA)

* * *

84. Plaintiff repeats and realleges each and every allegation set forth in the paragraphs above and further alleges the following.

85. The claims made in Count I of this Complaint are made against Danek and Sofamor-Danek.

86. The Luque II plate and screw device was developed by Eduardo Luque ("Luque") specifically for use in spinal surgery involving the lower back. The device consists of plates and screws which are intended to be attached to the lumbar spine with screws inserted posteriorly through the lumbar pedicles in order to provide a means of internal stabilization in connection with spinal fusion surgery.

87. On March 26, 1986, Warsaw Orthopedic submitted a 510(k) notification to the FDA for the Luque II device which was described as the "Interpeduncular Segmental Fixation System."

88. Less than two months later, on May 6, 1986, the FDA determined that the device was a Class III device which was not substantially equivalent to any pre-enactment device and which, therefore, could not be sold in the United States without a premarket approval based data developed in prospective clinical trials pursuant to an approved IDE. In explaining this decision, the agency stated that the decision was based on the fact that there had not been adequate demonstration that there was a pre-amendment device with a design substantially equivalent to The Luque System and on the fact that it posed potential risks not exhibited by other spinal fixation systems, such as:

"1. greater chance of neurological deficit due to imprecise screw placement or the event of screw failure;

2. pedicle fracture during placement of the screw;

3. soft tissue damage or inadequate fusion due to bending or fracture of device components; and

4. greater risk of pseudoarthrosis due to instability of design."

89. Determined to immediately sell the Luque II device for spinal fixation, Danek conceived and implemented an unlawful and deceptive scheme to bring the Luque II device to market without premarket approval and without the development of the kind of safety and efficacy data necessary to obtain such premarket approval.

90. The unlawful plan contemplated that:

(a) Danek would fraudulently seek 510(k) clearance of the components of the Luque II system as "bone plates" and "bone screws" for use in repairing fractures of the long bones even though the sole intended use of the Luque II system was in spinal applications;

(b) Once clearance from the FDA was obtained, Danek would contend that the FDA determination of substantial equivalence constituted official notification from the FDA that the devices were safe and effective and that such devices could be introduced for commercial use; and

(c) Consistent with Danek's goal to sell the Luque II device in interstate commerce for its intended use as a pedicle screw fixation device, Danek would promote the device by using physicians such as Luque to train other physicians in spinal applications of the Luque II device.

91. Using this approach, on June 5, 1986 Danek submitted a 510(k) notification for the same device components which made up the ISF system for which 510(k) clearance had previously been denied.

92. In the June 5, 1986 submission, the system components were described as "the Warsaw Orthopedic Bone Plate and Cancellous Bone Screw."

93. The notification claimed that "[t]he screws are designed for use in all fractures treated with two or more cancellous lag screws, such as intracapsular fractures of the hip and femoral condyle and tibia plateau fractures."

94. With respect to the plate components, the notification stated that "[s]pecific application is of course within the purview of the physician, but the use of the device in conditions such as long bone osteotomy, pelvic fracture and arthrodesis of the knee and/or ankle is obvious."

95. Subsequent correspondence with the FDA on behalf of Danek in connection with the notification emphasized that the device was intended for general orthopedic use in the long bones and not for pedicle fixation.

96. A July 2, 1986 letter written on behalf of Danek to the FDA in connection with the notification falsely stated that the Warsaw screws were "intended for use in the treatment and management of orthopedic injuries or conditions that in the view of the physician will benefit from the application of metallic screws or metallic plates and screws. Generally, this means for the repair of osseous fractures or conditions using screws having enhanced holding power in the cancellous bone."

97. Further misrepresentations appear in an August 1, 1986 letter written on behalf of Danek to the FDA regarding use of the cancellous bone screws, in which it was stated that "[t]he manufacturer intends that the screw will be used to treat fractures of cancellous bone."

98. In reasonable and justifiable reliance on the misrepresentations made regarding the intended use of the plates and screws which were the subject of the June 5, 1986 510(k) notifications, the FDA cleared these components as substantially equivalent to pre-amendment devices.

99. The representations made by Danek in obtaining these 510(k) clearances were intentionally false and

misleading. L.D. Beard, who at the time was the President and Chief Executive Officer of Danek, conceded at a deposition that the intended use of the bone plates and bone screws which were the subject of the June 5, 1986 510(k) notifications was not for repair of fractures of the long or flat bones as set forth in those 510(k) notifications. Rather, he admitted that the sole intended use of the system and system components was for use in spinal applications (i.e., pedicle screw fixation) and that the only reason why the FDA was told otherwise was so that clearance could be obtained so that the device could enter the market where Danek intended to promote and sell it only as a pedicle screw/spinal plate fixation system.

100. At the time the FDA made its substantial equivalence determination with regard to the Luque II device (which was presented to the FDA as "Warsaw Orthopedic Bone Plates and Cancellous Bone Screws"), it was ignorant of the fact that Danek had misrepresented the intended use of the Luque II Plates and Screws and that the sole intended use of the device components was as pedicle screws and spinal plates assembled as a spinal fixation system.

101. On June 27, 1986, an application was submitted for Danek to conduct clinical trials of the Luque Intrapeduncular Segmental Fixation System pursuant to the Investigational Device Exemption provisions of the Food, Drug and Cosmetic Act. The stated purpose of the IDE application was to develop data on the safety and effectiveness of the Luque II device for pedicular fixation.

102. The FDA granted approval to conduct the IDE trials involving a limited number of physicians and institutions.

103. However, the Luque II IDE failed to generate sufficient information on safety and efficacy to permit the FDA to grant premarket approval of the device for its intended use as a pedicle screw fixation device.

104. Nevertheless, Danek marketed and promoted the Luque II device on a massive basis outside of the IDE trial solely for its intended use as a pedicle screw fixation device.

105. Danek also manufactures, markets, distributes and sells the Texas Scottish Rite Hospital ("TSRH") spinal system. This instrumentation system was developed by Richard Ashman, Ph.D., ("Ashman"), John Herring, M.D. ("Herring") and Charles Johnston, M.D. ("Johnston") at the Texas Scottish Rite Hospital in Dallas, Texas.

106. The TSRH system employs a pair of rods arranged along the vertical axis of the spine which are connected to the vertebrae with hooks, screws or both.

107. Danek did not seek clearance from the FDA to market the screw components of the TSRH system for use in the pedicles of the lumbar vertebrae which, anatomically, lie above the bony base of the spine known as the sacrum.

108. However, it did seek 510(k) clearance for sacral application of the TSRH screws.

109. On September 2, 1988 a 510(k) notification was submitted to the FDA for what was described as TSRH "sacral screws."

110. Based on the representation that these screws were intended to be used in the sacrum, the FDA determined, on April 6, 1989, that the TSRH sacral screws were substantially equivalent to pre-enactment device components.

111. On September 12, 1990, Danek submitted a 510(k) notification to the FDA for the TSRH Variable Angle Sacral Screw.

112. The notification stated that the Variable Angle Sacral Screw was a modification of the TSRH sacral screw and followed the same intended use.

113. Based on the representation that these screws were to be used in the sacrum, the FDA determined on January 22, 1992 that TSRH Variable Angle Sacral Screw was substantially equivalent to a pre-amendment device.

114. The representations made in the 510(k) notifications to the FDA concerning the intended use of TSRH sacral and variable angle sacral screws were intentionally false and misleading.

115. At the time Danek submitted these 510(k) notifications, Danek intended that the screws which were labeled as "sacral screws" would be used by surgeons in the pedicles of the lumbar spine. Indeed, Danek funded a book which was authored by the developers of the system concerning its use. The book was specifically written to go along with the system as part of the system itself. It was to serve as a "cornerstone" for courses and workshops concerning the use of the system and "as a way to stimulate users' interest in purchasing and employing the instrumentation." One Chapter of this book, Chapter 5, is dedicated exclusively to a discussion involving the use of TSRH "sacral screws" in the pedicles of the lumbar spine in order to create a fixation construct for treatment of degenerative spinal instability. The text and illustrations in this regard are unmistakable. Chapters 4, 6 & 7 of the book also describe the use of TSRH screws in the lumbar pedicles. These chapters together account for over half of the book.

116. Consistent with this, Danek expressly viewed the TSRH system as a "pedicle screw fixation system."

117. Danek did request and receive approval to conduct IDE clinical trials involving 10 institutions and 240 subjects in order to obtain clinical data on the safety and efficacy of pedicle screw fixation with the TSRH system.

118. The TSRH pedicle screw IDE did not develop sufficient data to result in a successful application for premarket approval.

119. Nevertheless, Danek marketed and promoted the TSRH device on a massive basis outside of its IDE trial for its intended use as a pedicle screw fixation device.

120. Danek also manufactures, distributes and sells the so-called "Dyna-Lok" Spinal Fixation System. The system is a plate and screw device.

121. On September 7, 1991 Danek submitted at [sic] 510(k) notification for the Dyna-Lok Fixation System. The application falsely stated that the device was substantially equivalent to the Warsaw Bone Plate, now called the Danek

Plate, and that the bone screws used in the Dyna-Lok device were substantially equivalent to the TSRH Sacral Screw.

122. In reliance on Danek's representations concerning the intended use of the Dyna-Lok device, on December 17, 1992, the FDA determined that the device was substantially equivalent to pre-amendment devices.

123. Danek's 510(k) notification for the Dyna-Lok Fixation System misrepresented the intended use of the device. The device was designed and intended exclusively for use as a pedicle screw fixation device.

124. All of the misrepresentations made by Danek to the FDA as set forth in Count I of this Complaint were made intentionally to deceive the FDA and to induce it to issue 510(k) clearances for the Luque II, TSRH, and Dyna-Lok devices and device components in order to provide Danek with a pretext to claim that the devices could be lawfully introduced into interstate commerce.

125. The FDA was ignorant of the fact that these devices and device components were intended by Danek for use as pedicle screw fixation devices.

126. Were it not for these fraudulent acts and statements, the FDA would not have issued 510(k) clearances for Danek's pedicle screw fixation devices and device components for any purposes, the devices would not have been introduced into interstate commerce, and the Plaintiff would not have been exposed to the dangerous device which was surgically implanted in the Plaintiff.

127. The FDA, Plaintiff and Plaintiffs' implanting physicians relied upon Danek to make truthful statements to the FDA in its 510(k) notifications regarding the intended use of the devices at issue so that Plaintiff would not be implanted with a dangerous medical device that was never proven to be safe and effective for the use for which it was intended, i.e., pedicle screw fixation.

128. As a direct and proximate result of Danek's misrepresentations as set forth in Count I of this Complaint, Plaintiff suffered severe and permanent physical harm

including injuries to his spine, spinal nerves, spinal nerve roots and surrounding tissues, cells, nerves and vascular structures. As a result, Plaintiff has in the past and will in the future suffer a loss of earnings, an impairment in earning capacity, physical pain, mental anguish, emotional distress, permanent disability, liabilities for medical and rehabilitative expenses and other forms of damage, loss and harm.

* * *

B. The Intercompany/Association Conspiracy

* * *

238. By 1992, the manufacturers and sellers who marketed pedicle screw fixation devices in violation of federal law and the physicians and professional associations they conspired and acted in concert with expressed a need to find a means to avoid criminal prosecution and civil liability in connection with their past unlawful promotion of pedicle screw fixation devices and to legitimize the sale of such devices in the future.

239. In furtherance of the original goals of the intercompany/association conspiracy and as a means to avoid liability for past wrongful acts, those who participated in the intercompany/association conspiracy adopted and implemented a two-part scheme.

240. First, all of the members of the intercompany/association conspiracy agreed to the creation, funding, and support of a trade association which was named the Spinal Implant Manufacturers Group ("SIMG"), and a "Scientific Committee" to conduct a "Cohort Study" of pedicle screw fixation in a fraudulent and misleading manner and to use the "results" of this deceptive and misleading study:

(a) to achieve reclassification of pedicle screw fixation devices so that they could be legally marketed without the successful completion of prospective clinical trials and/or premarket approval;

(b) to avoid criminal prosecution for illegal sales and distribution of pedicle screw fixation devices; and

(c) to provide "scientific" evidence for use as part of a defense to litigation in which patients claimed that they suffered harm as a result of the use of pedicle screw fixation devices.

241. Pursuant to this scheme, data regarding the outcome of patients treated for spinal fracture and degenerative spondylolisthesis was gathered by SIMG, the Scientific Committee, AAOS, AANS, SRS, and NASS from spine surgeons who were selected to participate in the study; the data were received and analyzed by Biometric Research Institute, Inc. ("BRI"); and the results of the study were reported to an FDA advisory panel on July 22, 1994 and in a special issue of *Spine* magazine which was published on October 15, 1994.

242. Pursuant to the plan adopted by the members of the intercompany/association conspiracy, the manner in which the Cohort Study was conducted and reported was intentionally deceptive and materially misleading in that, among other things:

(a) In reporting the results of the study, it was claimed that the study represented an "independent" analysis of the safety and efficacy of pedicle screw fixation. However, the professional societies which designated representatives to serve on the Scientific Committee which was responsible for conducting the study (AANS, AAOS, SRS, and NASS), had significant financial relationships with the manufacturers and sellers of the pedicle fixation devices that were the subject of the Cohort Study which were not disclosed when the results of the study were reported;

(b) In reporting the results of the study, it was claimed that the study represented an "independent" analysis of the safety and efficacy of pedicle screw fixation. However, each of the members of the Scientific Committee which claimed responsibility for conducting the Cohort Study had a significant financial relationship with manufacturers of pedicle screw fixation devices, which became substantially

more generous on completion of the study. This circumstance was concealed from those to whom the study was reported.

(c) In reporting the results of the study, it was claimed that the study represented an "independent" analysis of the safety and efficacy of pedicle screw fixation. However, Hansen Yuan, M.D., who was chairman of the Scientific Committee which claimed responsibility for conducting the study was negotiating with two major pedicle screw manufacturers to license a new pedicle screw fixation device while the study was proceeding. Those manufacturers had made offers to pay him as much as one million dollars in cash and a percentage royalty worth as much as twenty-five million dollars for the license, making it explicit that the amount which Dr. Yuan would realize under these proposed arrangements was directly dependent on whether the FDA reclassified pedicle screw fixation devices as a result of the Cohort Study. Dr. Yuan concealed these transactions when the results of the Cohort Study were reported. Moreover, when Dr. Yuan was questioned concerning these transactions at a deposition and at a hearing, he falsely stated that he did not engage in these negotiations until the Cohort Study had been completed and gave false and misleading information concerning the agreement which he ultimately entered into for the licensing of the pedicle screw fixation system.

(d) In presenting the results of the Cohort Study to the FDA's advisory panel, the Scientific Committee represented that a sample of the Cohort study data was "assessed by an independent auditor pursuant to a plan which was based on a blinded, random site selection process" which demonstrated that the submitted data were accurate when, in fact, the only "audit" which was done was a revisit of five sites by a masters-level employee of Dr. Yuan, who later

admitted significant inaccuracies in data reporting and other material failures to comply with the study protocol.

(e) SIMG and the Scientific Committee adopted and implemented a policy to destroy virtually all documents related to the Cohort Study before the study was reported to the FDA advisory panel in violation of an existing document preservation order entered by a federal court and with the intent to destroy evidence concerning the manner in which the Cohort Study was created and implemented;

(f) BRI, which received and analyzed the Cohort Study data was directed by Order of the United States District Court for the Eastern District of Pennsylvania to produce all computer diskettes and documents in its possession concerning the study. Not only did BRI fail to comply with that order but it also falsely stated, under oath, that the computer diskettes in its possession concerning the study had technical defects which prevented it from making usable copies, that its computer backup system containing Cohort Study data had mysteriously "crashed," destroying the information encoded therein, and that it had virtually no documents in its possession concerning this study. After a lengthy hearing, however, it was "discovered" that BRI had usable computer diskettes which could be copied, that there was no "crash" of the BRI computer backup system and that BRI had boxes full of documents which were properly subject to production;

(g) In presenting the results of the Cohort Study, it was represented that the Cohort Study was "conducted" by the Scientific Committee and that the study data was collected or analyzed by the Scientific Committee when, in fact, the Scientific Committee was not familiar with the manner in which the study data was processed, the way in which it was verified, or the procedures which were developed and applied with regard

to missing, incomplete, and inconsistent data and did not perform or understand the statistical treatment of the Cohort Study data;

(h) The Cohort Study was purportedly designed to demonstrate the difference between the outcome of patients treated with pedicle screw fixation and the outcome of patients who were treated for the same conditions by other methods. However, the study intentionally distorted that comparison by excluding data from physicians who infrequently used pedicle screw fixation and frequently used other methods to treat the conditions under consideration;

(i) The physicians who participated in the study inaccurately reported the post-operative conditions of patients who underwent pedicle screw fixation surgery, selectively excluded data for patients who should have been included in this study and selectively included the data from patients who should have been excluded from the study;

(j) The study exacerbated the potential for reporting and selection bias by providing that data be submitted anonymously by spine surgeons; and

(k) In reporting the results of the study the fusion outcome in patients who received pedicle screw fixation surgery was falsely inflated in relation to the fusion rate achieved in patients who underwent fusion surgery without pedicle screw fixation.

243. To this date, Defendants involved in the Danek and intercompany/association conspiracies are attempting to use this fraudulent and misleading Cohort Study as a means of escaping liability in this and related litigation.

244. Beginning in the Spring of 1993, as the second aspect of the effort to achieve the legal marketing status for pedicle screw fixation devices through fraudulent and deceptive means, Danek and other manufacturers and sellers of pedicle screw fixation devices engaged in a collaborative industry-physician effort to deceive the FDA with respect to

the commercial use of a Harrington lag screw for pedicle fixation prior to 1976 in order to persuade the FDA that pedicle screws were substantially equivalent to pre-enactment devices and therefore deserving of 510(k) clearance without analysis of safety or efficacy.

245. Specifically, in furtherance of the goals of the intercompany/association conspiracy, AcroMed, Danek, Sofamor and Zimmer agreed to obtain fraudulent and false documents and testimony purporting to prove that Zimmer had made and sold a commercially available pedicle screw in the United States prior to May 28, 1976 and submit such documents and testimony to the FDA to secure 510(k) approval for the Danek TSRH system.

246. AcroMed, Danek, Sofamor and Zimmer knew that the position of the FDA was that Zimmer had not made and sold a pedicle screw in the United States prior to May 28, 1976 that would meet the pre-requisites of 510(k) clearance.

247. In fact, Zimmer's Director of Regulatory Affairs knew as early as November 1987 that the position of the FDA was that Zimmer had not made and sold a pedicle screw in the United States prior to May 28, 1976 that would meet the pre-requisites of 510(k) clearance.

248. Zimmer knew on or before May 20, 1992 that other manufacturers were "pursuing reclassification to pre-enactment status based upon some old Zimmer drawings found in a surgeon's files."

249. Rick Treharne of Danek called Michael Mayock of Sofamor, who was a former Zimmer employee, and requested that Mayock prepare an affidavit to be submitted with the Danek TSRH 510(k) application claiming falsely that Mayock had personal knowledge of a pre-enactment sale in the United States of a Zimmer pedicle screw.

250. Treharne and Mayock drafted numerous revisions of a proposed affidavit until Treharne composed and sent Mayock a document described by Treharne as the "perfect affidavit," which Mayock executed.

251. Mayock obtained approval from Sofamor before executing this "perfect" affidavit and another affidavit and then transmitted the same to Sofamor.

252. Mayock claimed in his affidavit that Zimmer made a pedicle screw product prior to May 28, 1976 that would meet the prerequisites of 510(k) approval, asserting falsely that Zimmer shipped a pedicle screw made by Zimmer in the United States to Zimmer distributor Keith Bartow, who then sold the screw to a Mexican doctor named Luque.

253. Keith Bartow did not sell pedicle screws made by Zimmer in the United States to Dr. Luque prior to May 28, 1976.

254. In fact, Keith Bartow did not even meet Dr. Luque until the early 1980's.

255. Danek Chief Executive Officer Beard called Zimmer President Ron Davis and requested that Zimmer perform research of pre-1976 pedicle screw usage to assist in Danek's TSRH 510(k) application.

256. Zimmer President Ron Davis instructed Zimmer General Counsel Timothy Wendt to conduct such research of pre-1976 pedicle screw usage to assist in Danek's TSRH 510(k) application.

257. AcroMed Director of Regulatory Affairs Christianson also called Zimmer General Counsel Timothy Wendt and requested that Zimmer perform research of pre-1976 pedicle screw usage to assist in Danek's TSRH 510(k) application.

258. In addition, Danek employee Bailey Lipscomb or Danek employee Rick Treharne called Zimmer's Director of Regulatory Affairs Max Sherman and requested that Zimmer conduct research of pre-1976 pedicle screw usage to assist in Danek's TSRH 510(k) application.

259. Sherman has testified that Zimmer had a policy against giving assistance to other manufacturers by providing them with supporting documents for 510(k) applications.

260. Nevertheless, Wendt ordered Zimmer employees to perform research of pre-1976 pedicle screw usage to assist in Danek's TSRH 510(k) application.

261. Zimmer did not charge Danek for its research of pre-1976 pedicle screw usage to assist in Danek's TSRH 510(k) application.

262. For pre-amendment status, FDA Compliance Policy Guide 7124.19 requires the following: (1) at least one United States sale pre-May 28, 1976 of a product made in the United States; (2) catalogue advertising; and (3) no research support. To prove the first point, the FDA requires either invoices or an affidavit explaining their absence.

263. Wendt executed two affidavits to be submitted to the FDA to assist in Danek's TSRH 510(k) application, explaining the absence of invoices purportedly proving at least one United States sale of a Zimmer pedicle screw pre-May 28, 1976.

264. Zimmer employee Gary Tanner prepared an affidavit to be executed by former Zimmer employee Ralph Welling that repeatedly used the term "pedicle screw" in reference to purported pre-May 28, 1976 screw usage by Zimmer, even though Welling had never before used the term "pedicle screw" or even heard such term before seeing his proposed affidavit.

265. Tanner prepared an affidavit to be executed by Ralph Welling that referenced purported pre-May 28, 1976 "pedicle screws" shipments and usage even though Welling had no personal knowledge whatsoever regarding whether or not the referenced screws were actually manufactured, sold or used.

266. The affidavits by Mayock, Wendt and Welling were essential to convince the FDA to approve the Danek TSRH 510(k) on the basis that they purportedly established that there was a United States pre-May 28, 1976 sale of a Zimmer "pedicle screw."

267. AcroMed, Danek, Zimmer and Sofamor knew that the factual claim in the Danek TSRH 510(k) filing that Zimmer made and sold a commercial pedicle screw in the United States that was not involved in research prior to May 1976 was false.

268. Indeed, Zimmer filed a "Supplemental Motion For Summary Judgment On The Plaintiffs' Conspiracy Claims And Zimmer, Inc.'s Brief In Support Of Supplemental Motion For Summary Judgment On The Plaintiffs' Conspiracy Claims" (hereinafter "Supplemental MSJ") on or about March 15, 1996 in MDL 1014, providing in pertinent part that:

(a) "Zimmer has never marketed any device which includes a screw intended for use in the lumbar pedicles" (p. 5);

(b) "Zimmer has never marketed a pedicle screw fixation system for use in the United States" (p. 10);

(c) "Zimmer does not now and has never marketed a spinal device which includes a screw intended for use in the lumbar pedicles of the spine" (p. 11);

(d) "Zimmer did not even have a product in the pedicle screw market" (p. 16);

(e) "The undisputed fact is that Zimmer did not have a product to sell in that market [pedicle screws]" (p. 17);

(f) "Zimmer never marketed a device that included a screw intended for use in the lumbar pedicles" (p. 18); and

(g) "Zimmer does not market a pedicle screw device" (p. 25).

269. Neither AcroMed, Danek, Sofamor nor Zimmer advised the FDA, and the FDA did not know, that Zimmer asserted that it "never marketed a pedicle screw fixation system for use in the United States," in direct conflict with the position set forth in the Danek TSRH 510(k) application.

270. Danek's Lipscomb and AcroMed's Christianson flew to Kansas together and collaborated on additional research for the Danek TSRH 510(k) application.

271. Sofamor employee Mayock testified that the joint research effort by AcroMed, Danek, Sofamor and Zimmer was "like a loose confederation."

272. Zimmer's Max Sherman stated in a July 14, 1989 memorandum that 510(k) approval for portions of Zimmer's

spinal implant system "would be a good defense item for litigation. (It would indicate Zimmer developed PSI using proper approval procedures.)"

273. AcroMed stated in a May 15, 1995 News Release (TMI 00686) that its first 510(k) clearance would "seriously undercut those allegations" by Plaintiffs "in the pending products liability litigation against AcroMed."

274. In 1995, Danek submitted a 510(k) notification requesting clearance to market pedicle screws for use in its TSRH system. The claim of substantial equivalence to a pedicle screw device in commercial distribution prior to 1976, which was necessarily required to obtain 510(k) clearance, was based primarily on the Mayock and Wendt affidavits, the former of which was overtly false, and the other, materially misleading.

275. Based on and in reliance on the representations and affidavits contained in Danek's 510(k) submission, on January 20, 1995, the FDA announced its determination that it had cleared pedicle screws pursuant to the Danek 510(k) premarket notification for limited indications. Subsequent clearances were granted to other manufacturers including AcroMed, SNR and Cross based on the Danek clearance.

* * *

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No. 98-1768

IN THE

Supreme Court of the United States

THE BUCKMAN COMPANY,
Petitioner,
v.
PLAINTIFF'S LEGAL COMMITTEE,
Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Third Circuit

MOTION FOR LEAVE TO FILE AND BRIEF FOR *AMICUS CURIAE* MEDICAL DEVICE MANUFACTURERS ASSOCIATION IN SUPPORT OF PETITIONER

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MOTION FOR LEAVE TO FILE *AMICUS CURIAE* BRIEF

Pursuant to Supreme Court Rule 37.2, the Medical Device Manufacturers Association ("MDMA") moves the Court for leave to file the attached *amicus curiae* brief in support of petitioner, The Buckman Company.[1] This case addresses the scope of product liability exposure in the medical device industry. As a national trade association representing nearly 130 independent manufacturers of medical devices, diagnostic products and health care information systems, MDMA is well-qualified to inform the Court of the great significance of this case for the medical device industry and the consuming public.

As MDMA's accompanying brief explains, direct conflicts in the lower courts over the scope of preemption have created a confusing pattern of tort liability exposure from state to state that threatens to disrupt nationwide availability of medical devices. In addition, the Third Circuit's holding that fraud on the agency claims escape preemption would undermine the public health by deterring beneficial "off-label" uses of medical devices and create delays in the Food and Drug Administration's premarket clearance of critical new devices. Furthermore, such fraud claims would allow private parties to seek remedies under state law that would interfere with the Food and Drug Administration's unique responsibility to investigate and punish fraud in its premarket clearance processes.

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[1] Counsel for petitioner consented to the filing of MDMA's brief, but counsel for respondent declined.

MDMA respectfully submits that it has the perspective to inform the Court about the significance of these issues that arise from this case, and that MDMA's brief would aid the Court in its decision regarding The Buckman Company's petition for certiorari. Accordingly, MDMA requests the Court to grant its motion to file the attached *amicus curiae* brief.

Respectfully submitted,

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BRIEF FOR *AMICUS CURIAE* MEDICAL DEVICE MANUFACTURERS ASSOCIATION IN SUPPORT OF PETITIONER

INTEREST OF *AMICUS CURIAE*

The Medical Device Manufacturers Association ("MDMA") is a national trade association based in Washington, D.C. that represents nearly 130 independent manufacturers of medical devices, diagnostic products and health care information systems. MDMA seeks to improve the quality of patient care by encouraging the development of new medical technology and fostering the availability of beneficial innovative products. To achieve these goals, MDMA represents its members' collective interests before the United States Congress, the Food and Drug Administration ("FDA"), other federal agencies, and courts that develop, implement or interpret policies that affect the medical device industry. MDMA has a significant interest in this case because it raises important product liability issues with broad implications for the entire medical device industry and the public health.[1]

SUMMARY OF ARGUMENT

The Court should grant the petition because it presents issues of critical importance to the public health, and because conflicting lower court decisions have created confusion and

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[1] No counsel for any party authored this brief in whole or in part, and no person or entity other than *amicus curiae* and its members made a monetary contribution to the preparation or submission of the brief.

uncertainty regarding the scope of tort liability in the medical device industry.

1. The Third Circuit held that the express preemption provision of the Medical Device Amendments of 1976 does not preempt state common law claims alleging fraud on the FDA. This case presents important public health questions, because if such claims are not barred by preemption, they will undermine the FDA's capacity to make critical new medical devices available promptly for patient treatment. Because most new medical devices cannot be marketed without prior FDA clearance, delays in the clearance process postpone availability of important therapies. Fraud on the agency claims such as those preserved by the Third Circuit would threaten delays in the FDA's premarket clearance process — and create associated delays in device availability — for two major reasons.

First, such claims would entangle agency personnel in tort litigation between private parties. The claims at issue in this case are premised upon the assertion that FDA product clearance was obtained through fraud. The FDA officials who granted clearance would be critical witnesses to the alleged fraud, because their personal knowledge primarily would determine whether a misrepresentation occurred, and if so, whether it affected premarket clearance of a medical device. Entangling FDA officials in tort litigation as witnesses would divert them from their important product clearance functions, thereby delaying the availability of critical medical devices.

Second, fraud on the agency claims would create incentives to burden the FDA with additional and unnecessary submissions of information. If fraud on the agency claims are preserved from preemption, as the Third Circuit held, manufacturers will attempt to protect themselves against fraud liability by submitting to the agency all information that is even arguably relevant to product

clearance, to guard against later allegations that there were material omissions in communications with the agency. The resulting burden on the agency to review the information submitted would further delay product clearances, with a corresponding detrimental effect on the public health.

2. This case also presents important public health questions because fraud on the agency claims would deter "off-label" use of medical devices. The FDA and the medical profession have long recognized that when the agency clears a product for one use, it may well have important unapproved uses as well. Cutting-edge therapies are frequently developed through off-label uses of devices cleared by the FDA for a different use. Fraud claims of the type at issue in this case — which allege that the manufacturer illegally promoted off-label uses — would deter companies from seeking FDA clearance for such uses. In addition, such fraud claims would deter dissemination of off-label use information to health care practitioners, even through dissemination is permissible under federal law.

3. Direct conflicts in the lower courts have created great uncertainty whether the MDA preempt *any* tort claims, and if so, whether fraud on the agency claims are preempted. As a result, a confusing pattern of liability exposure exists from state to state. The conflicts threaten to undermine nationwide availability of critical medical devices, because device manufacturers currently have a strong incentive to pick and choose the states where they will and will not sell their products. Only this Court can resolve the conflicts by granting the petition.

4. Fraud claims of the type preserved by the Third Circuit interfere with the FDA's unique responsibility to investigate and punish fraud in its premarket clearance processes. The FDA has extensive authority to remedy such fraud, and the proper role of a private party is to refer alleged frauds for investigation by the agency, not to pursue

independent remedies for fraud under state law. The Court should grant the petition to maintain the FDA's authority to remedy fraud on the agency.

ARGUMENT

I. This Case Presents Important Public Health Questions Because Claims for Fraud on the Agency Would Undermine the FDA's Capacity to Make Critical New Medical Devices Available Promptly for Patient Treatment

The Third Circuit held that the express preemption provision of the Medical Device Amendments of 1976 ("MDA") does not preempt state common law claims alleging fraud on the FDA. This case presents important public health questions, because if such claims are not barred by preemption, they will undermine the FDA's capacity to make critical new medical devices available promptly for patient treatment. Federal law prohibits manufacturers from distributing most new medical devices without prior clearance from the FDA (*see, e.g.*, 21 U.S.C. §§ 360e, 360(k) (1994 & Supp. 1999)), and as a result, delays in premarket clearance profoundly affect patients' health by postponing their access to innovative device therapies. The FDA has recognized the importance of streamlining its premarket clearance processes to "bring needed therapies to patients as quickly as possible." *Hearing Before the Subcomm. On Oversight & Investigations of the House Comm. On Commerce* (Sept. 23, 1997) (statement of Michael A. Friedman, Lead Deputy Commissioner, FDA). Yet fraud on the agency claims, such as those preserved from preemption by the Third Circuit, would hamper the FDA's ability to provide prompt premarket clearance for devices that could substantially improve the health of patients.

A. Fraud on the Agency Claims Would Delay Premarket Clearance by Entangling FDA Personnel in Litigation Between Private Parties

Until the Third Circuit's decision in this case, most lower courts had held (both before and after *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996)) that the MDA preempt claims for fraud on the FDA. *See* Pet. at 11-15. If such claims are instead preserved from preemption, as the Third Circuit held, they will increasingly cause delays in premarket clearance by entangling FDA personnel in litigation between private parties. Fraud claims such as those at issue here assert that misrepresentations were made to FDA officials responsible for premarket clearance decisions, who in turn authorized marketing of a medical device in reliance on the misrepresentations. These officials obviously would be critical witnesses to the alleged fraud in a tort suit, because their personal knowledge primarily would determine whether a misrepresentation occurred, and if so, whether it affected premarket clearance of a medical device.

Given their unique knowledge of the facts at issue in a fraud on the agency claim, FDA officials would be important witnesses for both the plaintiff and defendant. Indeed, in the present case, plaintiffs claim that defendants misled agency officials, yet defendants contend that their course of action (now alleged to be fraudulent) was *suggested* by the FDA. *See* Pet. at 17 n.8. For both parties, the witnesses who could provide the best evidence to resolve factual disputes like this one would be the FDA officials who reviewed and acted on the manufacturer's premarket clearance submissions.

Because they would be such important witnesses in fraud on the agency claims, FDA officials would be vulnerable to entanglement in tort litigation. Although the FDA, like other agencies, has promulgated "housekeeping" regulations that purport to restrict its obligation to respond to third party subpoenas issued in litigation between private parties, *see* 21

C.F.R. § 20.1, those regulations do not guarantee the agency any protection against involvement in tort suits. The regulations themselves authorize testimony if the public interest so requires. *See id.; In re U.S. Bioscience Sec. Litig.*, 150 F.R.D. 80 (E.D. Pa. 1993) (enforcing subpoenas for deposition testimony of FDA employees in private securities litigation).

Furthermore, at least since the Ninth Circuit's decision in *Exxon Shipping Co. v. Department of Interior*, 34 F.3d 774 (9th Cir. 1994), the lower courts increasingly have cast substantial doubt on the validity of such housekeeping regulations. In *Exxon*, the Ninth Circuit held that five federal agency heads could not rely on their agencies' housekeeping regulations to prevent subordinate employees from testifying pursuant to third party deposition subpoenas. The Ninth Circuit rejected the argument that this Court's decision in *United States ex rel. Touhy v. Ragen*, 340 U.S. 462 (1951) permitted federal agencies to refuse to allow their employees to respond to valid third-party subpoenas by invoking such regulations. *Exxon*, 34 F.3d at 778.[2] The court concluded

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[2] In *Touhy*, the Court held that an FBI official could not be held in contempt for obeying an order by his superior — the Attorney General — to refuse production of documents pursuant to a third-party subpoena. *Touhy* therefore addressed the question whether the Attorney General, as head of an agency, had authority to "centraliz[e] determination as to whether subpoenas *duces tecum* will be willingly obeyed or challenged" by implementing housekeeping regulations that "withdraw from his subordinates the power to release department papers." 340 U.S. at 467-68. The Court expressly refused to reach the question whether the agency

(Footnote cont'd on next page)

that just like any other witness, a federal employee witness is required to comply with a federal court subpoena under the standards set forth in Fed. R. Civ. P. 45. *Id.* at 779. Following *Exxon*, numerous other lower courts also have held that government agencies — including the FDA — may not rely on housekeeping regulations to withhold information sought through third-party subpoenas. *See, e.g., Houston Business Journal, Inc. v. Office of Comptroller of Currency*, 86 F.3d 1208, 1212 (D.C. Cir. 1996) (housekeeping regulations do not authorize withholding subpoenaed documents in conflict with Fed. R. Civ. P. 45); *Connaught Labs., Inc. v. SmithKline Beecham*, 7 F. Supp. 2d 477 (D. Del. 1998) (rejecting restrictions of FDA housekeeping regulations and enforcing subpoenas for testimony of FDA employees in patent litigation between private parties).

Once subpoenas were issued in a fraud case, the drain on the time and resources of agency personnel required for subpoena responses would be substantial. The scope of relevant testimony and documents potentially would be quite broad, because every communication between the manufacturer and the FDA regarding premarket clearance could be a source of evidence in a case alleging fraud on the agency, and such communications are numerous; the FDA's review of premarket clearance submissions is a collaborative process between the manufacturer and the agency, involving frequent dialog over a period of months or even years.

(Footnote cont'd from previous page.)

itself had a "privilege against disclosure" (*id.* at 468, 469 & n.9) allowing it to "refuse to produce government papers." *Id.* at 469.

For example, the agency has long encouraged early meetings between manufacturers and FDA officials to exchange information about a new device even before the FDA has approved clinical studies that may be required for eventual premarket clearance. *See Guidance on IDE Policies and Procedures* at 1 (Jan. 20, 1998) <http://www.fda.gov/cdrh>; *Goals and Initiatives for the IDE Programs* IDE Mem. #D95-1, at 2 (July 12, 1995) <http://www.fda.gov/cdrh/d951.htm1>. In 1997, Congress endorsed a similar interactive process by amending the Food, Drug, and Cosmetic Act to require the FDA, upon written request, to meet with the applicant for a premarket approval application ("PMA") within 100 days after the PMA is filed. 21 U.S.C. § 360e(d)(3). The agency does not limit itself to this required meeting and goes "beyond the [statutory] requirements by encouraging 'exploratory' meetings very early in the premarket review process and continued interactions throughout the review process." *FY 2000 Budget Request* at 1 <http://www.fda.gov/oc/oms/ofm/budget/devnctrtab.htm>. The FDA has agreed "to communicate with each firm at least every four weeks subsequent to the 100-day meeting." *FDA/CDRH Annual Report FY 1998* at 1 <http://www.fda.gov/cdrh/index.html>.

A fraud on the agency claim potentially would require FDA personnel to respond to discovery concerning each of these communications, thereby diverting substantial resources from review of premarket clearance applications. Distracting agency officials from their critical device review functions would undermine prompt clearance of promising new therapies that could substantially improve the public health.

B. Fraud on the Agency Claims Would Delay Premarket Clearance by Creating Incentives to Burden the FDA With Needless Submissions of Information

If fraud on the agency claims are preserved from preemption, as the Third Circuit held, they also will delay premarket clearance by creating incentives to burden the FDA with additional submissions of information. Manufacturers would attempt to protect themselves against fraud liability by submitting to the agency all information that is even arguably relevant to product clearance, to guard against later allegations that there were material omissions in communications with the agency. *See* Pet. at 18.

These additional information submissions would be unnecessary. For example, in the present case, the agency had no need for additional information to determine whether it had been defrauded. Only three months passed between the premarket clearance application that plaintiffs allege revealed defendants' true intended use (spinal surgery) and the application that plaintiffs allege fraudulently misrepresented the intended use as for the long bones in the arms and legs. Pet. App. at 5a. The FDA officials responsible for reviewing these applications manifestly had full notice that the intended use had been changed — and according to the petition had in fact *encouraged* the change (Pet. at 17 n.8) — at a time when it was well known at the agency that "[i]n practice, surgeons often use orthopedic screws which FDA has cleared for other purposes" in spinal surgery instead. *See* James M. Beck & Elizabeth D. Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 Food & Drug L.J. 71, 77 (1993) (citing FDA, Update on Pedicle Screws).

Though needless, the additional information submissions would have a deleterious effect on the FDA's product clearance work. Once the information was submitted, it

would need to be reviewed by FDA personnel who already have limited budgetary resources. Furthermore, in recent years, the number of FDA employees in the Office of Device Evaluation ("ODE") — the office responsible for reviewing premarket clearance applications — has steadily fallen. 1996 ODE Annual Report at 1; 1997 ODE Annual Report at 1; 1998 ODE Annual Report at 2, *supra*. Increasing the amount of information for these officials to review would increase product clearance times and delay the marketing of innovative therapies for patient use.

The tort system would create this effect after FDA, both on its own initiative and with Congressional urging, has made great strides to reduce clearance times by *diminishing* the information required to be submitted for agency review. *See, e.g.*, 21 U.S.C. § 360c(a)(3)(C) (requiring the FDA to consider "whether the extent of data that otherwise would be required for approval of the application with respect to effectiveness can be reduced through reliance on postmarket controls"). For example, the FDA now requires submission of less information for 510(k) applications regarding low risk devices (because clearance decisions are based primarily on descriptive information and a labeling review) than it does for high risk devices (for which clearance decisions rely on performance data). *The New 510(k) Paradigm* at 3 (Mar. 20, 1998) <http://www.fda.gov/cdrh/ode/parad510.html>. The agency also requires more information in a 510(k) application seeking initial clearance for a device than it does for an application seeking clearance for a change in a previously marketed device. *FY 2000 Budget Request* at 2, *supra*. To reduce submission requirements regarding 510(k) applications further, the FDA also permits manufacturers to certify compliance with certain material and performance standards in lieu of submitting information demonstrating compliance. *Id.* Because it has streamlined the submission process, FDA review time for 510(k) applications during

fiscal year 1998 was only *half* what it was only four years earlier. *FDA/CDRH Annual Report FY 1998* at 7, supra.

Fraud claims of the type preserved by the Third Circuit would undermine this important progress, with a corresponding detriment to the public health. In so doing, such claims would "stand[] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" (*Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)) — a circumstance that this Court has long viewed as giving rise to implied preemption of state law. This case therefore presents the Court with an excellent opportunity to address the federal-state balance in an area that directly affects the public health.

II. This Case Presents Important Public Health Questions Because Claims for Fraud on the Agency Would Undermine Valuable Off-Label Uses of Medical Devices

This case also presents important public health questions because fraud claims of the type at issue in this case would undermine "off-label" uses of medical devices. Judge Cowan's dissent below explained that "[t]he FDA and the medical community have long recognized the importance of doctors' off-label uses of medical products (uses not indicated on the label or approved by the FDA)." Pet. App. at 28a. Cutting-edge therapies are frequently developed through off-label uses of devices cleared by the FDA for a different use (*see, e.g., id.* at n.1), in part because medical science innovation moves at a faster pace than the agency's review process. As the discussion below explains, fraud claims of the type preserved by the Third Circuit would create incentives that undermine off-label uses and their related benefits to the public health.

A. Fraud on the Agency Claims Would Undermine Innovation by Discouraging Manufacturers From Seeking Premarket Clearance for Off-Label Uses

When it enacted the MDA, Congress intended to protect innovations in device technology from being "stifled by unnecessary restrictions" (H.R. Rep. No. 94-853 at 12 (1976)), thereby stimulating research and development of "sophisticated, critically important medical devices." S. Rep. No. 94-33 at 2 (1976). Yet as Judge Cowan properly noted in his dissent, the Third Circuit majority's preservation of fraud on the agency claims from preemption is "likely to hinder technological growth" (Pet. App. 27a) by discouraging manufacturers from seeking FDA premarket clearance for off-label uses.

Because many medical devices have multiple uses, it is not uncommon for a manufacturer to obtain premarket clearance for one use and later seek clearance for a different use. For example, a pain control device may be cleared by the FDA to treat pain of one particular cause and subsequently cleared for use to relieve pain of other causes, just as in the present case, the same orthopedic device was the subject of premarket clearance applications for use in two different skeletal structures. The FDA finds multiple applications for different uses of the same device unremarkable and considers each application independently on its merits. *See, e.g.*, 21 U.S.C. § 360c(i)(1)(E) (generally restricting agency review of intended use to consideration of the labeling submitted with 510(k) application). As Judge Cowan explained, expanding the uses for medical devices in this manner "will often be a very desirable source of progress and innovation in medical products." Pet. App. at 26a. It therefore is not surprising that when Congress amended the Food, Drug, and Cosmetic Act in 1997, it emphasized that it wanted "to encourage that these new uses be included on the product label." H.R. Conf. Rep. No. 105-399 at 99 (1997).

If fraud on the agency claims such as those at issue in this case were preserved from preemption, they would discourage manufacturers from seeking clearance for new uses. In the present case, the fraud claim rests on the premise that if the manufacturer has filed separate applications seeking clearance for two different uses of the same device, one must represent the true intended use, and the other must be fraudulent. Preserving such claims from preemption would make manufacturers concerned that in seeking clearance for new uses, they would render themselves vulnerable to tort claims for fraud relating to the clearance they received for the original use. The manufacturers would, in the words of Judge Cowan, consider themselves precluded, "via the penalty of fraud liability, from seeking approval for another use." Pet. App. at 26a. Because preserving such fraud claims from preemption would undermine the important public health benefits that derive from innovative new uses of medical devices, this case presents important issues worthy of Supreme Court review.

B. Fraud on the Agency Claims Would Chill Dissemination of Information Regarding Off-Label Use

Fraud on the agency claims of the type at issue in this case also would chill manufacturers' dissemination of information to health care practitioners regarding off-label uses, thereby undermining those uses and their associated benefits. If a manufacturer were deterred from seeking FDA clearance for the off-label use for the reasons described above, federal law would prohibit the manufacturer from affirmatively initiating dissemination of information regarding that use. Federal law permits manufacturers to initiate distribution of such information only if they submit an application seeking clearance for the off-label use, certify that they will submit such an application in the future, or

obtain an exemption from the agency. 21 U.S.C. § 360aaa-3(a).

Furthermore, fraud on the agency claims would deter manufacturers from disseminating off-label use information even if they did apply for an appropriate clearance. Judge Cowan was rightly concerned that following the Third Circuit's decision, a manufacturer might be exposed to fraud liability for "secur[ing] approval for one use" and "distribut[ing] materials on off-label uses in compliance with the statute . . . while its primary purpose is to obtain approval for the off-label uses." Pet. App. at 30a n.3. Judge Cowan properly perceived that in the hands of plaintiffs' counsel, off-label use information distributed by a manufacturer would be cast as evidence of alleged fraud on the agency, even if its dissemination was in full compliance with federal law. This exposure would further chill distribution of information regarding innovative therapies that benefit the public health.

III. The Court Should Grant the Petition to Maintain Nationwide Availability of Medical Devices by Establishing Uniformity in an Important Area of the Law Rife With Uncertainty and Conflict

When it enacted the MDA, Congress concentrated regulation of medical devices at the federal level, believing that it could minimize uncertainty, promote uniformity, and spur innovation that would not be "stifled by unnecessary restrictions." H.R. Rep. No. 94-853 at 12. One means of achieving this goal of uniformity was the MDA express preemption provision, which Congress intended to be a "general prohibition on non-Federal regulation." *Id.* at 45. In the wake of *Medtronic*, however, differing lower court opinions have undermined this intended uniformity, leaving the scope of the preemption provision — and the scope of tort liability for medical device manufacturers — plagued by uncertainty. The Court should grant the petition to clarify the

contours of the preemption provision and promote the uniformity intended by Congress.

The MDA express preemption provision invalidates certain state law requirements "establish[ed] or continue[d] in effect with respect to a device intended for human use." 21 U.S.C. § 360k. The Third Circuit held that fraud claims concerning the bone screw at issue in this case were not preempted because (*inter alia*) they did not establish "a state 'requirement' 'with respect to' that device." Pet. App. 13a. In so holding, the Court of Appeals appears to have joined the Tenth Circuit in concluding that tort claims in general are exempt from express preemption under section 360k. *See Oja v. Howmedica, Inc.*, 111 F.3d 782, 789 (10th Cir. 1997).

On this issue, the Third and Tenth Circuits are in direct conflict with the Fourth, Sixth, Seventh and Ninth Circuits, which hold that section 360k does encompass tort claims. *See Mitchell v. Collagen Corp.*, 126 F.3d 902, 912 (7th Cir. 1997), *cert. denied*, 118 S. Ct. 1300 (1998); *Papike v. Tambrands, Inc.*, 107 F.3d 737, 741 (9th Cir.), *cert. denied*, 118 S. Ct. 166 (1997); *Martin v. Telectronics Pacing Sys., Inc.*, 105 F.3d 1090, 1097-98 (6th Cir. 1997), *cert. denied*, 118 S. Ct. 850 (1998); *Duvall v. Bristol-Myers-Squibb Co.*, 103 F.3d 324, 330 (4th Cir. 1996). The petition makes clear that this conflict is magnified because in eight states within these Circuits, the applicability of preemption to tort claims differs depending upon whether a case is brought in state or federal court. *See* Pet. at 23-24 & n.14 (citing cases).

Furthermore, as the Third Circuit recognized, its opinion also established a direct conflict with the Seventh Circuit on the specific question whether fraud on the agency claims are preempted. *See* Pet. App. at 17a n.5 (citing *Mitchell*, 126 F.3d 902). And even within the Third Circuit, the scope of liability remains confused. The petition properly notes that the state law fraud claims preserved by the Third Circuit would impose a subjective test for determining the intended

use of a device, whereas federal law imposes a conflicting objective test. *See* Pet. at 27.

The obvious effect of the conflicts described above is that manufacturers currently face a pattern of differing tort liability exposure from state to state. For example, in the states of the Third Circuit, where manufacturers now may be sued (in federal court) for fraud on the agency as a result of the lower court's opinion, the scope of potential liability is extraordinarily broad. According to the Third Circuit, a plaintiff may prevail on such a claim simply by proving that a product clearance was obtained through fraud, and that the product caused injury. Pet. App. at 9a (citing elements of fraud cause of action), 18a (citing cases). The implication of the Third Circuit's analysis is that a manufacturer could be held liable for *any* injury caused by its product, even if it was not defective, and even if it was manufactured, designed and distributed with reasonable care and adequate warnings.

Given the vast differences in liability exposure in different jurisdictions, manufacturers of critical medical devices currently have a strong incentive to pick and choose the states where they will and will not sell their products. The conflicts therefore threaten to undermine the nationwide distribution of medical devices, leaving patients in some states without therapies that would prolong and enhance their lives. Nothing could be further from the result that Congress intended from a unified federal regulatory system with state interference proscribed by the preemption provision's "general prohibition on non-Federal regulation." H.R. Rep. No. 94-853 at 45.

As the petition notes, *see* Pet. at 20, the conflict on the question whether *any* tort claims are preempted derives from ambiguities in *Medtronic, Inc. v. Lohr*, and particularly from the opinions signed by Justice Breyer, who joined the Court's opinion (which casts doubt on MDA preemption of tort claims) but also authored a separate opinion emphasizing that

such preemption would not be "rare." 518 U.S. at 508. And the conflict on the specific question whether fraud on the agency claims are preempted stems at least in part from the fact that *Medtronic* did not address such a claim at all. *See* Pet. at 14. The lower courts cannot resolve these conflicts on their own. Only this Court can clarify the law in this important area and re-establish certainty and uniformity regarding product liability exposure for medical devices.

IV. The Court Should Grant the Petition to Prevent Interference with the FDA's Authority to Remedy Fraud in its Premarket Clearance Processes

The discussion above explains that Congress intended the MDA to establish a unified federal regulatory structure immune from state interference. State common law fraud claims such as those preserved by the Third Circuit would allow tort plaintiffs to interfere with the FDA's unique authority to police fraud in its own processes. In the present case, for example, the plaintiffs allege that the agency was defrauded, even though the agency — with all relevant facts before it — does not appear to agree. The Court also should grant the petition to prevent such intermeddling with the FDA's unique responsibility to remedy fraud in its premarket clearance processes.

Under federal law, the agency has extensive tools at its disposal to root out and punish fraud in its premarket clearance processes. The agency proceeds under its "fraud policy" to investigate "acts such as submitting fraudulent applications, making untrue statements of material facts, or giving or promising bribes or illegal gratuities [that] may call into question the integrity of some or all of the applicant's submissions to the agency." 56 Fed. Reg. 46,191, 46,199 (1991). If fraud is uncovered, the FDA exercises its authority "under applicable statutes and regulations, to refuse to approve the application (in the case of a pending application) or to proceed to withdraw approval (in the case of an

approved application)." *Id.* at 46,200. The FDA also refers fraud cases for criminal prosecution by the Department of Justice, because violation of the FDCA's prohibitions with "intent to defraud or mislead" is a felony. 21 U.S.C. §§ 331, 333(a)(2); *see also United States v. Cambra*, 933 F.2d 752, 755 (9th Cir. 1991) (FDCA felony provision prohibits fraud on government enforcement agencies). The federal Sentencing Guidelines include a sentencing enhancement for FDCA felony violations involving fraud if the government obtains a conviction. U.S.S.G. §§ 2N2.1(b)(1); 2F1.1.

In this regulatory scheme, with its "general prohibition on non-Federal regulation" (H.R. Rep. No. 94-853 at 45), the proper role of a private party is to *refer* alleged frauds to the agency for investigation, not to act as a private attorney general pursuing independent remedies under state law. For example, the FDA's "Citizens Petition" process allows any person to request the agency to withdraw a product clearance obtained through fraud. *See* 21 C.F.R. § 10.30. Respondent is well aware of this process, having filed a Citizens Petition (with 1,000 pages of supporting material) alleging fraud on the agency and seeking withdrawal of one manufacturer's bone screw product clearance. Citizens Petition, FDA Docket No. 98P-0623 (July 24, 1998). In addition, private parties may bring alleged frauds to the attention of the agency through contacts with FDA enforcement personnel. The Court should grant the petition for certiorari to keep responsibility for remedying fraud on the agency where it properly belongs — in the hands of the FDA.

CONCLUSION

For the reasons set forth above, the court should grant the petition for certiorari.

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June 2, 1999

(21)

No. 98-1768

IN THE

Supreme Court of the United States

THE BUCKMAN COMPANY,

Petitioner,

v.

PLAINTIFFS' LEGAL COMMITTEE,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

MOTION OF *AMICUS CURIAE* PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA FOR LEAVE TO FILE BRIEF *AMICUS CURIAE* IN SUPPORT OF THE BUCKMAN COMPANY'S PETITION FOR A WRIT OF CERTIORARI AND BRIEF *AMICUS CURIAE*

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The Pharmaceutical Research and Manufacturers of America ("PhRMA") hereby moves, pursuant to Supreme Court Rule 37.2, for leave to file a brief *amicus curiae* in support of The Buckman Company's petition for a writ of certiorari to the United States Court of Appeals for the Third Circuit. PhRMA is filing this motion because respondent has declined to consent to the filing by PhRMA of this *amicus curiae* brief.[1] A copy of the brief is attached.

As is more fully explained on pages 1-2 of the attached brief, PhRMA is a nonprofit association of the country's leading research-based pharmaceutical and biotechnology companies, which are engaged in the development of innovative medicines and medical devices. PhRMA's members are concerned that the lower court's erroneous decision that plaintiffs' "fraud on the agency" claims are not preempted by § 360k of the Medical Device Amendments of 1976, 21 U.S.C. § 360k (1999), to the Federal Food, Drug, and Cosmetic Act of 1938, 21 U.S.C. §§ 301-396 (1999), would, if left standing, have far-reaching and detrimental effects on the medical device and pharmaceutical industries, and on the public health.

PhRMA is uniquely positioned to assist the Court in this case because its members are subject to, and practically impacted by, the state and federal standards governing approval of devices and drugs. From this perspective, PhRMA can advise the Court regarding the disruptive impact of the decision below on the federal approval regime for devices and drugs. In particular, PhRMA can

1. In response to a request for respondent's consent to the filing by PhRMA of an *amicus curiae* brief in support of the petition, respondent's counsel replied verbally, on May 26, 1999, that respondent was declining to provide such consent.

demonstrate that allowing plaintiffs' "fraud on the agency" claims would impose an additional, burdensome state requirement on applicants for device and drug approvals; severely limit access to "substantial equivalency" approvals for medical devices; and reverse long-standing FDA policies regarding the propriety of so-called "off-label" uses of devices and drugs.

PhRMA also is well positioned to describe for the Court the stifling effect that the lower court's decision would have on the already lengthy and expensive development process for devices and drugs. PhRMA can demonstrate that the allowance of "fraud on the agency" claims such as plaintiffs' would significantly hinder the research, development, and sale of both new and "follow-on" devices and drugs, and would reduce the availability of such products to the public.

Accordingly, PhRMA respectfully requests that this Court grant leave to file the attached *amicus curiae* brief.

Respectfully submitted,

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INTEREST OF *AMICUS CURIAE*[1]

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is a voluntary, nonprofit association representing the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, healthier, and more productive lives.[2] PhRMA's

1. Pursuant to Supreme Court Rule 37.2(a), PhRMA hereby declares that, in response to a request for Respondent's consent to file a brief *amicus curiae*, Respondent's counsel verbally replied, on May 26, 1999, that Respondent was declining to provide such consent. A motion for leave to file a brief *amicus curiae* is attached to this brief. Pursuant to Supreme Court Rule 37.6, PhRMA also hereby declares that counsel for a party did not author this brief in whole or in part, and that no person or entity other than *amicus curiae*, its members, and its counsel has made a monetary contribution to the preparation or submission of this brief.

2. PhRMA's brief is submitted on behalf of PhRMA members Abbott Laboratories, Agouron, Allergan, Inc., Alza Corporation, American Home Products Corporation (and subsidiaries), Amgen, AstraZeneca PLC, Bayer Corporation (and subsidiaries), Biogen, Inc., Boehringer Ingelheim Corporation (and subsidiaries), Bristol-Myers Squibb Company (and subsidiaries), E.I. DuPont de Nemours & Company, Elan Pharmaceuticals, Fujisawa Healthcare, Inc., Genentech, Inc., Genzyme, Inc., Gilead Sciences, Inc., Glaxo Wellcome, Inc., Hoechst Marion Roussel, Hoffman-La Roche, Inc., Johnson & Johnson (and subsidiaries), Knoll Pharmaceutical Company, Eli Lilly and Company, The Liposome Company, Merck & Co., Inc. (and subsidiaries), Novartis Pharmaceuticals Corporation, Nycomed Amersham Imaging, Organon, Inc., Pasteur Merieux Connaught, Pfizer Inc., Pharmacia & Upjohn, The Procter & Gamble Company, Purdue Pharma L.P., Rhone-Poulenc Rorer, Inc., Sanofi Pharmaceuticals, Inc., Schering-Plough Corporation, Schwarz Pharma, Searle, Serono Laboratories, Inc., SmithKline Beecham Corporation (and subsidiaries), Solvay Pharmaceuticals, 3M Pharmaceuticals, and Warner-Lambert Company (and subsidiaries).

member companies invest nearly $24 billion annually in discovering and developing new medicines, leading the way in the search for cures. These companies are the source of the majority of new drugs that are discovered and marketed throughout the world. A number of PhRMA's members also are engaged in the development and sale of medical devices.

PhRMA estimates that, currently, the average cost of developing a single new drug is approximately $500 million. Testing and obtaining FDA approval for a specific indication(s) of a new drug requires approximately fifteen years.[3] The length of this process already significantly cuts into the patent protection period that affords manufacturers their best opportunity to recover these enormous development costs. *See* 35 U.S.C. § 154 (1994). Extending and increasing the cost of the regulatory process by adding pre-approval burdens arising from state law would diminish the economic feasibility of new device and drug development, to the detriment of PhRMA's members and the public health.

PhRMA's members are deeply concerned that the lower court's decision, unless reviewed and reversed, would effectively rewrite long-standing FDA rules governing the approval of new drugs and medical devices. The lower court's decision squarely conflicts with established FDA practice by allowing states to require that applicants for FDA approval, under the threat of fraud liability, claim as "intended uses" all known or foreseeable uses of each new product. Such state-mandated disclosures, unless preempted, would force applicants to establish the safety

3. This total includes time spent on: (1) "pre-clinical" testing; (2) clinical testing of the drug on human populations; and (3) applying for and awaiting final FDA approval.

and efficacy of all known or foreseeable uses in seeking federal approval. The inevitable result of placing these additional state requirements on manufacturers would be to delay, or even eliminate, the availability of many new and competitive devices and drugs.

For these reasons, PhRMA joins The Buckman Company in urging this Court to accept review in this case, and to reverse the lower court's holding on the preemption issues presented for review.

REASONS FOR GRANTING THE WRIT

The lower court upheld plaintiffs' "fraud on the agency" claims against express preemption challenges under § 360k of the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. § 360k(a) (1999), to the Federal Food, Drug, and Cosmetic Act of 1938 ("FDCA"), 21 U.S.C. §§ 301-396 (1999), and implied preemption challenges under the Supremacy Clause, U.S. Const. art. VI, cl. 2. Appendix to Petition for a Writ of Certiorari, The Buckman Company, No. 98-1768, at 25a (filed May 3, 1999) (hereafter "Petitioner's Appendix"). In so doing, the lower court read this Court's decision in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), to create a presumption against preemption of claims based on state laws of general applicability. Petitioner's Appendix at 12a-13a. The court also concluded that imposing state fraud liability on petitioner would merely reinforce duties of candor imposed by FDA regulations and the federal criminal code. *Id.* at 13a (citing 21 C.F.R. § 807.87(j); 18 U.S.C. § 1001). Both of these conclusions were erroneous, and led to a misapplication of the MDA's preemption clause that will bring state law and the federal regulatory scheme into direct conflict.

As discussed more fully below, the lower court's primary analytical mistake was its failure to recognize the specific elements of the "fraud on the agency" alleged by plaintiffs. The particular "fraud on the agency" claimed by plaintiffs is the alleged suppression of petitioner's *subjective* intent regarding the uses of the bone screws manufactured by its client, AcroMed Corporation. Plaintiffs claim that petitioner joined in misrepresenting to the FDA that the screws were intended to be used to treat "long bone" injuries of the arms and legs. *Id.* at 8a. In truth, according to the complaint, petitioner understood that the screws would be used for pedicle (spinal) surgery, a use well-established in medical practice, but not approved by the FDA. *Id.* at 8a-9a; *see also id.* at 28a-29a n.1 (Cowen, J., dissenting) (discussing the FDA's recognition that pedicle use of bone screws, while not federally approved, is nonetheless widespread).

According to plaintiffs, petitioner's fraudulent statement regarding "intended use," which was consistent with the labeling and promotional materials submitted to the FDA, resulted in FDA approval of the marketing of AcroMed's screws. *Id.* at 8a-9a. Because the screws were allowed onto the market, physicians were able to use them in pedicle surgeries, notwithstanding the absence of FDA approval of the screws for that use. *Id.* at 9a. Plaintiffs claim that the pedicle surgeries that allegedly caused them harm would never have been performed but for the availability of AcroMed's screws. *Id.*

In considering the preemption questions, the lower court failed to define with precision the fraudulent act at issue. Instead, the court addressed its analysis to "fraud" on a general level, holding that, because federal law prohibits

"fraud," plaintiffs' "fraud on the agency" claims merely paralleled the requirements of federal law. *Id.* at 13a. In making this broad assertion, the lower court overlooked the inevitable divergence it was creating between federal and state device application requirements.

The FDA's long-standing practice in reviewing both medical device and drug applications is to consider the safety and efficacy of those "intended uses" for which a manufacturer seeks labeling and promotional authorization. *See Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51, 55 (D.D.C. 1998), *order amended*, 36 F. Supp. 2d 16 (D.D.C. 1999), *and amended*, 36 F. Supp. 2d 418 (D.D.C. 1999); *see also* 21 C.F.R. §§ 807.87(e), 807.92(a)(5) and 814.20(b)(3)(i) (1998) (a manufacturer seeking approval of a new device must state the device's "intended uses"). As Judge Cowen noted in dissenting below, the FDA and applicant-manufacturers recognize the possibility, and in some cases the virtual certainty, that devices and drugs approved for one "intended use" will be employed by physicians for other "off-label" uses. Petitioner's Appendix at 28a-29a (Cowen, J., dissenting); *see also Friedman*, 13 F. Supp. 2d at 56 (noting that "off-label" use is "an established aspect of the modern practice of medicine."). Because Congress has disavowed any interest in regulating the practice of medicine, *see* 21 U.S.C. § 396 (1999), the FDA has made no effort to eliminate "off-label" use of approved devices and drugs, and such use has become the standard of care in many fields of medicine. *See, e.g.*, 60 Fed. Reg. 51946, 51947 (1995) (discussing the FDA's recognition, since 1992, that pedicle fixation with bone screws has constituted the standard of care in the surgical community).

Undercutting this established federal practice, the "fraud on the agency" claims upheld below would subject manufacturers to potential state liability (including punitive damages) whenever "off-label" uses of approved products cause harm. Only by disclosing all known or foreseeable uses to the FDA, and undertaking to prove them safe and effective, could a manufacturer avoid the threat of potentially massive "fraud on the agency" liability of the type alleged by plaintiffs. Thus, the existing federal regime — which permits manufacturers to market a product, under controlled labeling and promotional restrictions, so long as *any* safe and effective use is established — would be transformed into a regime in which market access is denied unless *all* known or foreseeable uses are shown to be safe and effective.

As further explained below, the extension of the approval process to unclaimed, but known or foreseeable, uses at the very least adds a state-based requirement to the MDA approval regime, and thus runs afoul of 21 U.S.C. § 360k. In addition, the disclosure requirement effectively imposed by the lower court's decision would slow, and in some cases foreclose, market access for new products, particularly for "follow-on" drugs and devices for which, as here, "off-label" uses are established. This result would contravene the legislative scheme and purposes of the MDA and FDCA, and accordingly should be foreclosed by established principles of implied preemption. *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941).

I.

THE LOWER COURT'S RULING THAT THE PLAINTIFFS' "FRAUD ON THE AGENCY" CLAIMS ARE NOT PREEMPTED MUST BE REVIEWED AND REVERSED.

In analyzing a preemption question, a court must engage in a precise comparison of the conduct required by the state claim with that mandated by federal law. Only in this manner can a reviewing court determine whether the state claim is in conflict with the express mandates of federal law, and/or with the overarching purposes of the federal legislative scheme. *See Medtronic*, 518 U.S. at 504-05 (opinion of Breyer, J.) (stating that state common-law actions may be preempted if they require conduct that is different from or additional to that required by federal law, and positing that a state negligence action based on the use of a 1-inch hearing aid wire should be preempted by a federal regulation requiring 2-inch wires).

This logical, comparative analysis was used by the Seventh Circuit in *Mitchell v. Collagen Corp.*, 126 F.3d 902 (7th Cir. 1997), *cert. denied*, 118 S. Ct. 1300, 140 L. Ed. 2d 467 (1998). The *Mitchell* court recognized:

> [I]n order to determine whether a common law cause of action is preempted by the action of the FDA, it is necessary to examine the state law cause of action at a sufficiently precise level of generality to determine whether the final judgment of the state court would impose on the manufacturer a burden incompatible with the requirements imposed by the FDA.

Id. at 912. The *Mitchell* court engaged in a claim-by-claim comparison of state- and federally-mandated conduct, and found that, to the extent the conduct required by the plaintiffs' strict liability, negligence, mislabeling, misbranding, adulteration, "fraud on the agency" and implied warranty claims was additional to or different from that required under federal law, such claims were preempted by § 360k. *Id.* at 913-15.

In this case, by contrast, the lower court failed to analyze the precise conduct required by plaintiffs' "fraud on the agency" claims. Consequently, it failed accurately to compare such claims with the requirements of the MDA, and with the overarching purposes of the federal regime. As a result of this threshold analytical error, the lower court found several generalized grounds for rejecting preemption of plaintiffs' claims.[4] Analyzed with particularity, however, it becomes evident that plaintiffs' claims are barred by both express and implied preemption principles.

The claims before this court are narrowly defined. They do not allege injury caused by fraudulent marketing, false promotion, mislabeling, or misbranding of AcroMed's bone

4. First, the court apparently concluded that, because plaintiffs' claims alleged "fraud" — which is generally proscribed by federal law — they simply mirrored federal regulations, and did not impose different or additional state law requirements upon applicants for medical device approval. Petitioner's Appendix at 13a. Alternatively, the court concluded that, even if plaintiffs' claims established additional state requirements, such requirements were not specific to petitioner's device, and were therefore not expressly preempted by the MDA. *Id.* Lastly, the court found that allowing a state-based remedy for "fraud" by medical device manufacturers and their agents would not thwart the purposes of the federal regulatory scheme. *Id.* at 16a-17a.

screws. Nor do they involve contentions that the bone screws were defectively manufactured or designed, or that they were used in an improper "off-label" manner. Instead, as discussed above, plaintiffs raise the limited allegation that the *very existence of the screws on the market* — facilitated by petitioner's "fraud on the agency" — caused them "harm."[5]

The particular "fraud on the agency" allegedly perpetrated by petitioner is similarly limited in scope. Plaintiffs do not claim that petitioner falsified any data. They claim instead that petitioner committed "fraud" by failing to disclose to the FDA its subjectively "intended uses" for AcroMed's bone screws. Petitioner's Appendix at 8a-9a.

As such, the narrow preemption question presented by this case is this: Does the MDA expressly or impliedly preempt a state law requirement that applicants for medical device approval disclose to the FDA their subjective intent or knowledge with respect to the known or foreseeable uses to which the device will be put by unrelated persons?

Contrary to the lower court's finding, the answer to this question must be "yes." Plaintiffs' "fraud on the agency" claims are expressly preempted by the MDA, as they would

5. In fact, plaintiffs could not have made any of the above allegations in the lower court because petitioner — the sole party certified on appeal to that court — acted only as a regulatory consultant to AcroMed during the FDA approval process, and did not participate in manufacturing, marketing, or other external activities. *See* Petition at 5-6; Petitioner's Appendix at 8a-9a (describing the plaintiffs' allegations).

impose an additional state requirement of "full disclosure" on applicants for medical device approval. Moreover, plaintiffs' claims are impliedly preempted because they would severely disrupt the federal approval scheme for devices and drugs, and would work against the public health objectives of the MDA and FDCA.

A. Plaintiffs' "Fraud On The Agency" Claims Are Expressly Preempted By The Medical Device Amendments Of 1976.

The preemption clause of the MDA precludes the establishment or continuation of any state requirement with respect to a medical device that is different from, or in addition to, the federal requirements applicable to the device. 21 U.S.C. § 360k(a) (1999). Plaintiffs' "fraud on the agency" claims are preempted under these terms, for allowing such claims would add a state-based requirement to the federal device approval process.

Federal law does not require manufacturers of medical devices (or their agents) to reveal their subjective "intended uses" for a device for which they are seeking FDA approval. In fact, judging "intended use" based on subjective intent is directly contrary to the federal regulatory scheme. The MDA's implementing regulations define "intended use" in an objective fashion. 21 C.F.R. § 801.4 (1998) (providing that the "intended use" of a device is determined by "the objective intent of the persons legally responsible for the labeling of devices."); *see also* 59 Fed. Reg. 59820, 59822 (1994) (acknowledgment by the FDA that "[a] product's intended use is usually primarily a function of the manner in which a company characterizes its product in the marketplace."). Under the regulations, objective intent is

determined by examining the manufacturer's proposed labeling and conduct, not by a speculative inquiry into the subjective expectations or knowledge of the manufacturer or its employees. 21 C.F.R. § 801.4.[6]

Indeed, interpreting the term "intended use" subjectively, or to include unclaimed, but known or foreseeable, uses defies both federal intent and common sense. Neither manufacturers nor the FDA can lawfully control the uses to which their devices are put by healthcare providers. It is irrelevant to the FDA whether a manufacturer subjectively "intends" or desires for any particular "off-label" uses to be adopted. All that is relevant to — and reasonably discernible by — the FDA is the manufacturer's expressed intent, as evidenced by its conduct in labeling, advertising, and marketing its devices. *See id.* Moreover, it would be administratively difficult, if not impossible, for the FDA to determine, at the approval stage, whether a manufacturer has truthfully revealed all of its subjectively intended uses for a product.

Because plaintiffs' "fraud on the agency" claims hold manufacturers liable for failing to make an additional, "subjective intent" disclosure, they impose a requirement under state law that is "in addition to" established federal requirements. Accordingly, such claims are expressly preempted by § 360k.

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6. In fact, Congress has recently expressly recognized the objective nature of the "intended uses" disclosure. *See* 21 U.S.C. § 360c(i)(1)(E) (1999) ("Any determination by the Secretary of the intended use of a device shall be based upon the proposed labeling submitted in a report for the device under section 360(k) of this title.").

B. Plaintiffs' "Fraud On The Agency" Claims Are Impliedly Preempted Because They Are In Direct Conflict With The Purposes Of The MDA and FDCA.

More fundamentally, plaintiffs' "fraud on the agency" claims inherently clash with and obstruct achievement of the overarching purposes of the MDA and FDCA. Such claims will work to stifle the research and development of new and "follow-on" medical devices and medicines, to the detriment of the general public health.

Under the analysis delineated by this Court, a federal statute impliedly preempts any state law that either actually conflicts with the federal law, or "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995) (quoting *Davidowitz*, 312 U.S. at 67). A majority of this Court in *Medtronic* recognized that state law claims against medical device manufacturers could be subject to preemption under these principles. 514 U.S. at 503, 507-08 (plurality opinion and opinion of Breyer, J.). In this case, allowance of "fraud on the agency" claims will have both of these impermissible effects.

1. Sustaining The "Fraud On The Agency" Claims Alleged By Plaintiffs Would Severely Limit "Substantial Equivalency" Approvals For Medical Devices, And Would Hinder The Research And Development Of New Devices And Drugs.

Most strikingly, "fraud on the agency" claims such as plaintiffs' would likely severely hinder the ability of medical device manufacturers to seek expedited "§510(k)" approval

based on a device's "substantial equivalency" to a preexisting device. *See* 21 U.S.C. § 360e(b)(1)(B) (1999). To that extent, such claims would bring state law into direct conflict with the federal legislative scheme, and would frustrate legislative goals by stifling the dissemination of competitive "follow-on" medical devices.

Under § 510(k), a medical device manufacturer seeking to sell a new device may avoid the rigorous "premarket approval" process, and instead obtain expedited FDA approval, by demonstrating that the device is "substantially equivalent" to a preexisting device. *Id.*; *see also Medtronic*, 518 U.S. at 477-79. A manufacturer seeking § 510(k) approval must submit a "premarket notification" to the FDA describing, among other things, the "intended uses" of the device. 21 C.F.R. § 807.92(a)(5) (1998). If the FDA determines that the proposed device is "substantially equivalent" to its predecessor for the specified "intended uses," it will grant approval. *Id.* § 807.100.

Importantly, a manufacturer cannot secure § 510(k) approval for a device with materially different or additional "intended uses" from those of its predecessor. 21 U.S.C. § 360c(i)(1)(A)(1999) ("substantial equivalence" of devices requires that the devices have the same intended uses); 21 C.F.R. § 807.100(b)(1) (1998). Thus, where a new device claims uses in addition to those of its predicate, its manufacturer cannot obtain expedited approval to market the device.

Under the "fraud on the agency" claims alleged by plaintiffs, however, device manufacturers and their agents face potentially massive fraud liability for *failing* to seek approval for all known or foreseeable uses of the devices

they wish to market. Plaintiffs harmed by allegedly known or foreseeable "off-label" uses could allege, as in this case, that the manufacturer "subjectively intended" the device to be put to the use in question, and defrauded the FDA by failing to reveal such intent.

A manufacturer could defend itself from "fraud on the agency" claims such as these only by disclosing to the FDA all known or foreseeable uses, and seeking either approval or "contraindication" labeling therefor. This is because, with respect to any "off-label" use for which labeling is *not* sought, plaintiffs could assert that the manufacturer "subjectively intended" the use to be adopted, and failed to reveal such intent to the FDA.[7] As a result, a manufacturer's only affirmative defenses to a "fraud on the agency" claim would be either: (1) that the manufacturer *did* subjectively intend for the "off-label" use in question to be adopted, *and* disclosed such intent to the FDA by seeking approval for that use; or (2) that the manufacturer *did not* intend such use, and proved as much by seeking "contraindication" labeling.

Practically, to protect themselves from "fraud on the agency" claims of the type plaintiffs allege, manufacturers would be forced to abandon the § 510(k) "substantial equivalency" process, and submit their devices instead to the "premarket approval" process. This would radically

7. Indeed, this is precisely what plaintiffs claim here: despite the fact that the FDA had actual knowledge that the bone screws would be used in pedicle surgery (by virtue of AcroMed's prior applications for such use), plaintiffs maintain that petitioner and AcroMed "defrauded" the FDA in failing to seek approval for that use at the same time they sought approval for "long bone" use. Petitioner's Appendix at 5a, 8a-9a.

change the current trend in device approval applications, *see Medtronic*, 518 U.S. at 479-80 (reporting that, in 1990, 80% of new Class III devices were approved through the § 510(k) mechanism), and would thwart the salutary legislative purposes for which the expedited approval scheme was enacted. *Id.* at 478 (noting that the scheme was intended to "prevent manufacturers of grandfathered devices from monopolizing the market while new devices clear the PMA hurdle, and to ensure that improvements to existing devices can be rapidly introduced into the market[.]").

As a result, plaintiffs' "fraud on the agency" claims would bring state law into irreconcilable conflict with § 510(k), and with the intent of Congress in enacting that amendment to the FDCA. Accordingly, such claims are barred under traditional principles of "conflict" preemption. *See id.* at 507-08 (opinion of Breyer, J.) (citing *Davidowitz*, 312 U.S. at 67).

In addition to directly undermining the § 510(k) process, plaintiffs' "fraud on the agency" claims would interfere with the federal regulatory scheme regarding "breakthrough" device approvals. Because the threat of "fraud on the agency" liability would force manufacturers to rigorously test for all potential uses, disclose their test results to the FDA, and seek labeling therefor, plaintiffs' claims would work to significantly slow the already laborious process of researching, testing, and seeking approval for new, beneficial devices. As a result of this slowing, there would be reduced availability of innovative products to the public. This adverse consequence conflicts with the MDA's goal of ensuring the ready availability of safe and effective medical devices. *See* H.R. Rep. No. 94-853, at 12 (1976).

Additionally, the disruptive effects of the allowance of plaintiffs' "fraud on the agency" claims would likely spill over to the drug approval regime. Drug manufacturers are required, in seeking FDA approval, to list the intended indications of the drug in question. *See* 21 C.F.R. § 314.50(c)(2) (1998). As a result, "fraud on the agency" claims such as those alleged by plaintiffs could (and likely would) be asserted against such manufacturers any time an allegedly known or foreseeable "off-label" use of a drug caused injury. To avoid exposure to "fraud on the agency" claims, drug manufacturers likely would be forced to shoulder the same pre-approval burden as medical device manufacturers – namely, testing and seeking labeling for all known or foreseeable uses of proposed drugs.

As is true with respect to medical devices, "fraud on the agency" liability likely would slow all drug approvals, and severely limit availability of the "abbreviated" approval process for "generic" drugs. Under the FDCA, a drug manufacturer may submit an Abbreviated New Drug Application ("ANDA") seeking expedited FDA approval for a "generic" drug that is essentially identical to a "listed" drug. 21 U.S.C. § 355(j) (1999); 21 C.F.R. § 314.92(a) (1998) (ANDAs may be submitted for drugs that are "identical in active ingredient(s), dosage form, strength, route of administration, and conditions of use[.]"). As is the case under § 510(k), an ANDA may seek approval *only* for the same uses previously approved for the listed drug; manufacturers may not use the application to seek approval for additional uses. 21 U.S.C. § 355(j)(i); 21 C.F.R. § 314.94(a)(4).

If plaintiffs' "fraud on the agency" claims are allowed, however, manufacturers seeking ANDA approval may be

faced with liability for "fraud" if they fail to seek federal approval for all allegedly known or foreseeable uses.[8] Given this significant risk, manufacturers likely would be forced to abandon the ANDA process altogether. The end result – diminished availability of competitive alternative medicines – would be directly at odds with Congress' intent in enacting the ANDA provisions in 1984. *See, e.g.*, H.R. Rep. No. 98-857, pt. 1, at 14 (1984) (stating that the legislation's purpose was "to make available more low cost generic drugs by establishing a generic drug approval procedure for pioneer drugs first approved after 1962.").

In sum, the allowance of plaintiffs' "fraud on the agency" claims would effectively eviscerate approval for "follow-on" medical devices, and would hinder the development and marketing of innovative new devices. These disruptive effects could spill over to the drug approval context. Because plaintiffs' claims would create significant disharmony between state law and the terms and goals of the federal approval scheme, they are impliedly preempted.

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8. This dilemma frequently would arise in the generic drug context. Once a "brand-name" drug entered the market, physicians would be free to adopt "off-label" uses for the drug. Thus, by the time a generic drug manufacturer submitted an ANDA (in an attempt to provide an alternative to the consuming public), there almost certainly would be known "off-label" uses of the drug. Generic drug manufacturers would risk "fraud on the agency" claims such as plaintiffs', however, if they chose to submit the ANDA in the statutorily required manner — that is, without seeking approval for such "off-label" uses.

2. Sustaining Plaintiffs' "Fraud On The Agency" Claims Would Undermine Long-Standing FDA Policies Regarding "Off-Label" Uses.

In a related respect, plaintiffs' "fraud on the agency" claims would disrupt the delicate balance struck by the FDA with respect to the proper role of manufacturers in facilitating "off-label" uses of approved devices and drugs.

As noted above, the FDA has long accepted "off-label" use as a rational and beneficial part of the practice of medicine. *See* 59 Fed. Reg. 59820, 59821 (1994) (noting that the FDA has long held that " 'unlabeled' uses may be appropriate and rational in certain circumstances, and may, in fact[,] reflect approaches to drug therapy that have been extensively reported in medical literature."); *see also Friedman*, 13 F. Supp. 2d at 55-56. Consequently, such uses are prevalent, especially in important fields such as oncology and pediatrics. *Id.* at 56. In some areas of practice, such uses constitute the standard of good medical care. *Id.*

The FDA, while attempting to regulate the manner and extent to which manufacturers can participate in the development and dissemination of information regarding "off-label" uses, also has recognized the need for adequate information regarding such uses. *See id.* at 56-58. As Judge Cowen stated in dissent, given the FDA's acceptance of "off-label" uses, "difficult and subtle balancing is called for in evaluating manufacturers' roles in the creation and distribution of information about [such] uses[.]" Petitioner's Appendix at 30a; *see also* 59 Fed. Reg. 59820, 59823 (1994).

Plaintiffs' "fraud on the agency" claims would wreak havoc on this balancing by forcing manufacturers, to the extent they are able, to eliminate "off-label" uses entirely. As discussed above, to avoid massive "fraud" liability, manufacturers would seek to include as many uses as possible "on-label." Further, manufacturers would be discouraged from contributing to efforts to study and provide information regarding alternative uses of their products, since such efforts might be viewed as evidence of their "subjective intent" with respect to such uses. Thus, plaintiffs' "fraud on the agency" claims could curtail "off-label" uses in a sweeping and misdirected manner that is discordant with the federal regulatory scheme.

In sum, the injection of plaintiffs' state-based "fraud on the agency" claims into the federal approval process would bring state law into irreconcilable conflict with the MDA and FDCA regimes, and would have significant adverse effects on medical device and drug manufacturers, and on the public health. These effects fully warrant this Court's review and reversal of the lower court's holding that plaintiffs' "fraud on the agency" claims are not preempted.

CONCLUSION

For all of the foregoing reasons, this Court should grant the petition on the questions presented, and reverse the lower court's decision.

Respectfully submitted,

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No. 98-1768

In the Supreme Court of the United States

BUCKMAN COMPANY, PETITIONER

v.

PLAINTIFFS' LEGAL COMMITTEE

ON PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

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2699

QUESTION PRESENTED

Whether federal law preempts state-law tort claims alleging fraud on the Food and Drug Administration during the regulatory process for marketing clearance applicable to certain medical devices.

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In the Supreme Court of the United States

No. 98-1768

BUCKMAN COMPANY, PETITIONER

v.

PLAINTIFFS' LEGAL COMMITTEE

ON PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

This brief is filed in response to the Court's order inviting the Solicitor General to file a brief expressing the views of the United States.

STATEMENT

Respondents claim that they suffered injuries from the implantation of orthopedic bone screws into the pedicles of their spines. They allege that petitioner fraudulently obtained regulatory clearance for the manufacturer to market the pedicle screws by misrepresenting to the Food and Drug Administration (FDA) that the screws were "intended for use in appropriate fractures of long bones of both the upper and lower extremity and such other flat bones," even though, respondents contend, the screws were designed and sold "exclusively for use in the spine." Pet. App. 8a. The question presented is whether, as petitioner contends, that claim of "fraud on the FDA" is preempted by federal law.

1. a. The Federal Food, Drug and Cosmetic Act (FDCA), 21 U.S.C. 301 *et seq.*, as amended, empowers the FDA to regulate a wide variety of products. The Medical Device Amendments of 1976 (MDA), Pub. L. No. 94-295, 90 Stat. 539, supplemented the FDCA's original provisions by creat-

ing a federal program to enhance "the safety and effectiveness of medical devices intended for human use" (90 Stat. 539 (Preamble)). See *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470, 475-477 (1996). The MDA authorizes the FDA to undertake specified review, clearance, approval, and other regulatory activities with respect to medical "devices," which include instruments, implants, and similar articles that are intended for use in the treatment, mitigation or prevention of disease or to affect the structure or function of the body. See 21 U.S.C. 321(h) (defining "device"), 360c-360*l* (1994 & Supp. IV 1998) (regulatory program).

The MDA directs the FDA to group medical devices into three classes, based on the degree of regulation it concludes is necessary to provide reasonable assurance of safety and effectiveness. 21 U.S.C. 360c(a) (1994 & Supp. IV 1998); see *Medtronic*, 518 U.S. at 475-476. Class III devices are those that present "a potential unreasonable risk of illness or injury." 21 U.S.C. 360c(a)(1)(C). The makers of Class III devices are subject to a variety of controls and to the FDA's statutory "premarket approval" (PMA) process. 21 U.S.C. 360c(a)(1)(C) and 360e(a). To obtain a PMA, the manufacturer must submit detailed information to provide the FDA with reasonable assurance that the device is safe and effective for its intended use. 21 U.S.C. 360c(a)(1)(C), 360e(a) and (c); 21 U.S.C. 360e(d) (Supp. IV 1998); 21 C.F.R. Pt. 814.[1]

Class III devices that were on the market before the MDA's enactment, however, may be marketed without FDA review until the FDA, by rulemaking, requires the submission of a PMA. 21 U.S.C. 360e(b)(1)(A). In the interest of

[1] Class I devices are those that present no unreasonable risk of illness or injury and are subject to only minimal regulation through "general controls." 21 U.S.C. 360c(a)(1)(A). Devices that are potentially harmful are Class II devices; they may be marketed without advance approval, but manufacturers must comply with federal standards known as "special controls." 21 U.S.C. 360c(a)(1)(B). See *Medtronic*, 518 U.S. at 476-477.

fairness and to prevent the "grandfathered" manufacturers from monopolizing the market, the FDA also permits other manufacturers to distribute similar devices by showing (through a premarket notification process) that they are "substantially equivalent" to the grandfathered devices. 21 U.S.C. 360e(b)(1)(B). That procedure is known as the "Section 510(k) process," referring to the FDCA section codified at 21 U.S.C. 360(k). See *Medtronic*, 518 U.S. at 478-479.

When respondents were allegedly injured by the pedicle screw spinal system at issue in this case, the FDA had not yet classified that device. The FDA subsequently classified and reclassified pedicle screw spinal systems intended for certain uses as Class II devices, subject to special controls. See 63 Fed. Reg. 40,025 (1998); 21 C.F.R. 888.3070(a); pp. 13-14, *infra*. Pedicle screw spinal systems intended for all other uses are Class III devices. See 21 C.F.R. 888.3070(b).

b. The MDA contains an express preemption provision, 21 U.S.C. 360k(a), which provides:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

See also 21 U.S.C. 360k(b) (permitting FDA to grant exemptions from preemption).

This Court addressed Section 360k's preemptive effect in *Medtronic*. There, the plaintiffs sought damages for injuries caused by a pacemaker, which, they alleged, was defectively

designed, built, and manufactured. The FDA had cleared the pacemaker, a Class III medical device, for distribution under Section 510(k) on the ground that it was "substantially equivalent" to a pre-MDA device. Medtronic, the manufacturer, contended that Section 360k preempted plaintiffs' tort claims. This Court disagreed.

The Court first held that Medtronic's compliance with the Section 510(k) process did not impose any "requirements" on the device—and thus did not preempt plaintiffs' design defect claims—because the FDA's clearance did not "require" the pacemaker "to take any particular form for any particular reason." 518 U.S. at 493; accord *id.* at 513 (O'Connor, J., concurring in part and dissenting in part) (Section 510(k) process "places no 'requirements' on a device" and therefore does not preempt design defect claims). The Court next held that Section 360k did not preempt state-law claims in which the duty of care was based on FDA requirements, because those claims did not subject Medtronic to state-law requirements that were "different from, or in addition to," the federal requirements. *Id.* at 495. The Court noted that the FDA's interpretive regulations "expressly support the conclusion that § 360k 'does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the Act.'" *Id.* at 496-497 (quoting 21 C.F.R. 808.1(d)(2) (1995)).

Finally, the Court held that Section 360k did not preempt the plaintiffs' claims based on negligent manufacturing and labeling. 518 U.S. at 497-502. The Court recognized that FDA regulations set out general "requirements" for manufacturing and labeling medical devices. *Id.* at 497. It concluded, however, that Section 360k does not mandate preemption of state-law requirements with respect to a device unless, as suggested in FDA regulations interpreting Section 360k, the FDA has adopted specific counterpart regulations or other specific substantive requirements applicable to the particular device. *Id.* at 498-500 (citing 21 C.F.R.

808.1(d) (1995)). The Court therefore concluded that the "entirely generic" federal manufacturing and labeling requirements did not provide a basis for preemption of the general state common law duties at issue in that case. *Id.* at 501; see also *id.* at 505- 507 (Breyer, J., concurring in part and concurring in judgment). In his separate opinion, Justice Breyer, agreeing with Justice O'Connor's opinion for four Justices (see *id.* at 509-512), concluded that, ordinarily, insofar as the MDA preempts a state requirement embodied in a statute or regulation, it also preempts a similar state requirement that takes the form of a standard of care imposed by state tort law, *id.* at 503-505; but he concurred in the Court's holding that the federal manufacturing and labeling requirements were not sufficiently "specific" to trigger preemption, *id.* at 505-508.[2]

2. Petitioner, a regulatory consultant, was retained by the AcroMed Corporation, a medical device manufacturer, to act as its liaison to the FDA. In September 1984, petitioner, on behalf of AcroMed, made a submission for Section 510(k) marketing clearance for an orthopedic bone screw device known as the Variable Screw Placement (VSP) Spinal Plate Fixation System. Petitioner's submission stated that Acro-

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[2] As we informed the Court in a response to the Court's invitation in a subsequent case presenting preemption issues under the MDA, in 1997 the FDA proposed an interpretive rule to give further guidance on the meaning of Section 360k. See U.S. Amicus Br. 19-20, *Smiths Indus. Med. Sys., Inc.* v. *Kernats*, cert. denied, 522 U.S. 1044 (1998) (No. 96-1405). That rule would have expressly construed Section 360k, consistent with the opinions in *Medtronic*, to preempt a common law duty only when (1) the FDA has imposed, by regulation or order, a specific substantive requirement applicable to a particular medical device, and (2) state common law imposes a substantive requirement applicable to the same medical device that is different from, or in addition to, the FDA's counterpart requirement. 96-1405 U.S. Br. App. 9a-15a, 17a-18a. After further consideration, the FDA withdrew that proposed rule. See 63 Fed. Reg. at 39,789. That withdrawal has no bearing on the preemption question presented here, and the interpretation of Section 360k in this brief is consistent with the interpretation in the proposed rule and in our brief in *Smiths Industries*.

Med intended to market the device for use in spinal surgery. The FDA denied the request, finding that the VSP device was a Class III device and was not substantially equivalent to any predicate device marketed before the MDA's enactment. In September 1985, petitioner filed a second submission for marketing clearance, again stating that the device was intended for use in spinal surgery. The FDA again denied the submission on the ground that the device was not substantially equivalent to any predicate device and that it posed potential risks not exhibited by other spinal-fixation systems. Pet. App. 4a-5a.

In December 1985, petitioner and AcroMed made a different attempt to obtain marketing clearance through the Section 510(k) process. They split the VSP device into its two component parts, which they called "nested bone plates" and "cancellous bone screws," and they filed separate Section 510(k) submissions for each component. Those submissions stated that the devices were intended to be used in long bones of the arms and legs. After reviewing the submissions, an FDA official contacted petitioner for additional information about the intended use of the device. Petitioner responded that "[t]he proposed indications for use for the AcroMed device are the same general indications proposed for the AO system of plates [which were marketed before the MDA's enactment] . . . [and] are intended for use in appropriate fractures of long bones of both the upper and lower extremity and such other flat bones (as in the fractured pelvis)." C.A. App. A58. In February 1986, the FDA granted marketing clearance for AcroMed's bone plates and screws for this stated purpose. Pet. App. 5a.

3. a. Respondents are some of the more than 5000 plaintiffs who filed suits alleging that they were injured when their doctors inserted the assembled VSP device into their spines. More than 2300 individual suits were brought against multiple defendants, and those suits were consolidated for pre-trial proceedings in the Eastern District of Pennsylvania pursuant to the multi-district litigation statute, 28 U.S.C. 1407 (1994 & Supp. IV 1998). Pet. App. 1a; Pet. 6.

The only count against petitioner is one that respondents call "fraud on the FDA." Pet. App. 5a. That count asserts that petitioner "intentionally and falsely" told the FDA that the AcroMed bone plates and screws were intended for use in fractures of long bones, when, in reality, the "sole intended use of these components was as an assembled [VSP] spinal plate/pedicle screw fixation system." C.A. App. A57, A58. Respondents allege that AcroMed designed the devices to be used exclusively in the spine and that petitioner "sought approval of [the] VSP plates and screws for use in the long bones simply as a pretext in order to market the device for its true intended use in the spine." *Id.* at A58. Respondents further allege that the FDA did not know that the bone plates and screws "were intended by AcroMed to be used as pedicle screw fixation devices," and that if petitioner had not made false statements about their intended use, the FDA would not have cleared the devices for marketing, the devices would not have been sold, and respondents thus would not have been harmed by them. *Id.* at A63.

The district court initially dismissed the "fraud on the FDA" claims on the ground that they were preempted by the MDA. Pet. App. 53a. Relying on the Third Circuit's decision in *Michael* v. *Shiley, Inc.*, 46 F.3d 1316, 1329, cert. denied, 516 U.S. 815 (1995), the district court reasoned that Section 360k "does not permit courts to 'perform the same function initially entrusted to the FDA,'" Pet. App. 49a, and that the FDA is in the "best position" to decide whether a manufacturer "withheld material information from the agency and, if so, [to determine] the appropriate sanction." *Id.* at 50a (quoting *Reeves* v. *AcroMed Corp.*, 44 F.3d 300, 306 (5th Cir.), cert. denied, 515 U.S. 1104 (1995)).

After this Court decided *Medtronic*, respondents asked the district court to reinstate their "fraud on the FDA" claims. Pet. App. 7a. Although the court indicated that this

Court's decision in *Medtronic* foreclosed a finding of express preemption under Section 360k, *id.* at 40a, it nevertheless dismissed respondents' claims on the grounds that they improperly assert a private right of action for violation of the MDA and that the target of the alleged fraud was the FDA, not respondents. *Id.* at 36a-40a. In the alternative, the court dismissed the claims because "the alleged fraud * * * cannot be said to have been a proximate cause of [respondents'] alleged injuries." *Id.* at 41a.

b. A divided panel of the court of appeals reversed. Pet. App. 1a-32a. The court held that Section 360k does not expressly preempt the claims, because there is neither a federal "requirement" "applicable to the device" nor a state "requirement" "with respect to" that device. *Id.* at 13a. Moreover, the court reasoned, the "state common law relied upon [by respondents] does not impose any obligation on [petitioner] inconsistent with federal law," because it is a crime to make a false statement to a federal agency, see 18 U.S.C. 1001 (1994 & Supp. IV 1998), and because FDA regulations require those who seek FDA clearance of devices under Section 510(k) to vouch for the truthfulness and accuracy of their submissions. Pet. App. 13a; see note 5, *infra*.

The court of appeals also rejected the district court's conclusion that the "fraud on the FDA" claims constitute an impermissible attempt to obtain a private right of action for violations of the MDA. Pet. App. 14a-17a. Although the court of appeals itself had relied on similar reasoning in *Michael*, the court found such reasoning inconsistent with this Court's intervening decision in *Medtronic*. *Id.* at 16a. The court therefore disagreed with *Mitchell* v. *Collagen Corp.*, 126 F.3d 902, 914 (7th Cir. 1997), cert. denied, 523 U.S. 1020 (1998), a post-*Medtronic* decision in which the Seventh Circuit had followed *Michael* and held that a "fraud on the FDA" tort claim was preempted. Pet. App. 17a n.5.

Finally, the court of appeals reversed the district court's decision to dismiss the claims for the additional reason that

they fail to allege a sufficient causal connection between the asserted fraud and respondents' injuries. Pet. App. 19a-21a. Because neither the parties nor the district court had analyzed the choice-of-law issues raised by the complaint or discussed the law of any particular jurisdiction that would govern the causation element of such a claim, the court of appeals found it impossible to determine whether respondents "have or have not alleged a legally sufficient causal nexus." *Id.* at 21a.

Judge Cowen dissented. Pet. App. 25a-32a. He expressed concern that "recognizing a state cause of action for violations of FDA regulations will greatly distort the penalty scheme established by the statute," because the "penalties attached to a violation of the FDA's regulations will often be substantially increased, and enforcement of violations will no longer be controlled by the FDA's prosecutorial discretion." *Id.* at 28a.[3]

DISCUSSION

As petitioner correctly contends, the decision below squarely presents at least one issue that has divided the lower courts: whether federal law preempts a state-law cause of action based on a defendant's alleged fraud on the FDA during the regulatory process for marketing clearance applicable to certain medical devices. That issue is important, and this Court should grant certiorari to resolve it.

1. On the merits, we agree with petitioner that respondents' "fraud on the FDA" claim is foreclosed by federal law, but we disagree on why that is so.

a. Contrary to petitioner's contention (Pet. 26-27), the court of appeals was correct in holding that the claim is not expressly preempted by Section 360k. As a general matter,

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[3] The Third Circuit returned to this case in *In re Orthopedic Bone Screw Prods. Liability Litigation*, 193 F.3d 781 (1999), which involved issues arising under certain of plaintiffs' other claims against a variety of defendants. That decision has no bearing on this petition.

a defendant claiming preemption under Section 360k must show, at a minimum, that the application of state law would impose obligations in addition to or different from "specific counterpart regulations" or a federal requirement that is "specific" to a "particular device." *Medtronic*, 518 U.S. at 500 (internal quotation marks omitted); accord *id.* at 506-507 (opinion of Breyer, J.).

Petitioner has identified no such specific federal requirement applicable here. It contends instead that respondents' claim is preempted because it "would threaten to impose liability for failing to disclose in the 510(k) process information that the FDA itself does not require." Pet. Reply Br. 10. But the federal requirement that petitioner argues would be impermissibly supplemented by respondents' state law theory of liability—the requirement that the person making a Section 510(k) submission identify the device's "intended use"—applies to such devices generally; it does not impose a requirement specifically with respect to the VSP device that is the subject of these consolidated cases. See 21 C.F.R. 807.87(e) (1985 & 1999). Compare *Medtronic*, 518 U.S. at 501; *id.* at 506-507 (opinion of Breyer, J.). For that reason, even if (as petitioner contends) respondents' claim depends upon the existence of a state-law duty to provide the FDA with information about intended or "off-label" uses in addition to the information that federal law requires to be disclosed, that claim would not be expressly preempted, because the federal duty of disclosure is insufficiently device-specific to trigger preemption under Section 360k.[4]

[4] Petitioner argues that this case implicates a conflict concerning a separate issue: whether *Medtronic* exempts from express preemption *all* state requirements that are imposed through state tort law of general applicability. See Pet. 19-25. As we explained in our brief in *Smiths Industries* (at 17-18, 19), it is our view that Section 360k does preempt a specific duty of care that is made applicable to a device through a State's common law of torts if that requirement is different from, or in addition to, a specific requirement imposed by the FDA. See *Medtronic*, 518 U.S. at 503-505 (opinion of Breyer, J.); *id.* at 509-512 (O'Connor, J., concurring in part and dissenting in part). See note 2, *supra*. Although we agree that the lower courts are divided on that issue, this case would likely prove to be an inappropriate vehicle for trying to resolve it. The cases underlying that conflict generally involve ordinary product defect claims. As discussed in the text, Section 360k is inapplicable here for reasons independent of whether the application of state tort law is insufficiently specific to be preempted by that provision, and this Court would therefore probably find it unnecessary to resolve the latter issue. As we discuss below, however, this case *does* implicate a separate conflict concerning whether federal law preempts state-law claims of fraud on a federal agency, and certiorari would be appropriate to resolve *that* issue.

In any event, even if the general duty to provide truthful information to the FDA about a product's "intended use" *were* device-specific enough to preempt state-law duties to provide additional information, respondents' claim still might not fall within the scope of Section 360k, because, on the present record, it is not clear that the asserted state common law duty on which respondents rely would, as applied here, be "different from, or in addition to," that federal duty. See *Medtronic*, 518 U.S. at 495; see also *id.* at 513 (O'Connor, J., concurring in part and dissenting in part). Petitioner argues that those state and federal duties are in fact different. Petitioner reasons that it *did* disclose the "intended use" of the device at issue—which petitioner appears to equate with whatever use is stated in the device's labeling (Pet. 27)—and that any liability must therefore rest on a violation of a further duty under state law to disclose any foreseeable off-label uses and any plans to market the device for those uses. See *ibid.*; Pharmaceutical Research and Manufacturers of America (PhRMA) Br. at 10-11.

That argument is unavailing, at least at this stage of the litigation. As the court of appeals recognized (Pet. App. 23a-24a), respondents' theory of liability does not appear to be that petitioner and its clients obtained a Section 510(k) clearance for one bona fide intended use while failing to disclose a foreseeable off-label use. Nor, in the claim at issue here, do respondents seek to hold petitioner liable for giving a physi-

cian information about an off-label use that was not identified in the Section 510(k) submission. See *id.* at 24a n.7; cf. *In re Orthopedic Bone Screw Prods. Liability Litigation*, 193 F.3d 781, 787 (3d Cir. 1999). Instead, respondents claim that AcroMed's bone plates and screws were never meant to be used at all for the intended use set forth in the Section 510(k) submissions; instead, respondents contend, the ostensible intended use was merely a pretext to get the device on the market, where it would be used exclusively for other (uncleared) uses. See Pet. App. 23a-24a; C.A. App. A57, A58.

Under the FDA's regulations, the "intended use" of a medical device is defined by the "objective intent of the persons legally responsible for the labeling of [the] device[]." 21 C.F.R. 801.4. That objective intent may be determined by (for example) labeling claims, advertising materials, written or oral statements, or the circumstances in which the device is offered and used. *Ibid.*; see also 21 C.F.R. 801.5. The complaints in this case allege that the devices at issue were meant solely for use in the spine, and that petitioner's representation to the FDA that the devices were intended for use in long bones was therefore false and misleading. C.A. App. A57, A58. Because that factual allegation has not been fleshed out in proceedings in the various district courts, it is impossible on the present record to say that any duty under state law would be "different from, or in addition to," applicable duties under federal law.[5]

[5] See 18 U.S.C. 1001 (1994 & Supp. IV 1998) (prohibiting false or fraudulent statements on any matter within the jurisdiction of a federal agency); 21 C.F.R. 807.87(k) (promulgated in 1992, see 57 Fed. Reg. 18,062, 18,064, 18,066 (1992)) (requiring each person submitting premarket notification to state that, "to the best of his or her knowledge," all "data and information" are "truthful and accurate" and that "no material fact has been omitted"); 21 C.F.R. 807.87(h) (1985) (requiring, during the period relevant here, that parties submitting premarket notification must provide the FDA with "[a]ny additional information regarding the device requested by the Commissioner that is necessary for the Commissioner to make a finding as to whether or not the device is substantially equivalent to a device in commercial distribution").

That is *not* to say that any representation to the FDA about a device's intended use must disclose every foreseeable use of the device. Physicians often employ medical devices for uses that are not identified in the labeling, and manufacturers may seek Section 510(k) clearance for the use identified in the labeling without setting forth every possible off-label use to which the device might be put after it reaches the market. But, for obvious reasons, the intended use stated in the premarket notification must be a bona fide use of the device; it cannot be a mere pretext calculated to clear the device for distribution exclusively for other uses.[6]

b. The present record also provides little support for petitioner's alternative contention (Pet. 27-29) that respondents' claim would "conflict" with the FDA's 1998 decision to classify and reclassify pedicle screw spinal systems for certain uses as Class II devices.[7] The FDA's classification and

[6] It is inaccurate to suggest, as petitioner does (Pet. 27; see also PhRMA Br. 10-11 & n.6), that the FDA never inquires, and lacks authority to inquire, into off-label uses in connection with premarket notification submissions under Section 510(k). Although 1997 amendments to the FDCA confine FDA's determination of the intended use of a device, for purposes of a Section 510(k) clearance, to its proposed labeling, see 21 U.S.C. 360c(i)(1)(E)(i) (Supp. IV 1998), the FDA may nonetheless "require a statement in labeling that provides appropriate information regarding a use of the device not identified in the proposed labeling" if the FDA determines "that there is a reasonable likelihood that the device will be used for an intended use not identified in the proposed labeling for the device," and "that such use could cause harm." 21 U.S.C. 360c(i)(1)(E)(i)(I)-(II) (Supp. IV 1998). FDA recently explained that, "[w]hile this is a new statutory requirement, it is important to note that it is not different from the manner in which 510(k)s have traditionally been reviewed." Office of Device Evaluation, Center for Devices and Radiological Health, FDA, *Determination of Intended Use for 510(k) Devices—Guidance for Industry and CDRH Staff* 1 (Jan. 30, 1998).

[7] Tort claims may be subject to conflict preemption under the MDA even if they are not expressly preempted under Section 360k. See *Medtronic*, 518 U.S. at 502-503; *id.* at 507-508 (opinion of Breyer, J.).

reclassification decision—which occurred long after the underlying events at issue here (see Pet. App. 5a)—was based on "new information," including studies conducted years after petitioner obtained Section 510(k) clearance for AcroMed's devices. See 63 Fed. Reg. at 40,025-40,026. That decision operates prospectively and does not legitimize conduct that was previously impermissible. *Id.* at 40,037-40,038. Moreover, the FDA classified and reclassified pedicle screw spinal systems as Class II devices only for certain spinal uses, and it imposed four "special controls" requiring that the devices' labeling contain a special warning and that they comply with material standards, mechanical testing standards of performance, and biocompatibility standards. See *id.* at 40,027, 40,034-40,038. The sample complaint relied on by the court of appeals does not indicate whether AcroMed's devices were marketed for the uses for which the devices are now classified as Class II or whether their manufacture and composition were consistent with the special controls that the FDA has now prescribed. See Pet. App. 8a-9a; C.A. App. A42-A131. For these reasons, petitioner has not established that a tort judgment for respondents would contradict the FDA's 1998 determination; and, in any event, the allegedly tortious actions occurred before that determination.

c. Nevertheless, in our view, federal supremacy principles do preclude respondents' "fraud on the FDA" claim.

Respondents' claim is quite peculiar. It is independent of any claim against the manufacturer of the device in question, and it apparently does not depend on any showing that the device was somehow defective, or falsely advertised, under state law. See Pet. App. 8a-9a. Instead, respondents simply contend that, but for petitioner's alleged misrepresentations to the FDA, the agency would not have cleared the device for marketing, the device would not have been marketed, and it therefore would not have harmed respondents. *Ibid.* The focus of the claim is therefore not on the device itself or on any provisions of state law that might apply directly to

the device or to its manufacturing and distribution, but rather solely on the character of the relationship between petitioner and the federal government. Absent a contrary direction by Congress, that relationship is, as a general matter, governed by federal not state law.

In the typical preemption context, when Congress legislates "in a field which the States have traditionally occupied," preemption analysis begins "with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Medtronic*, 518 U.S. at 485 (quoting *Rice* v. *Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). The common law duties at issue in *Medtronic*, concerning the manufacture and distribution of a device that was allegedly defective under state law, fell squarely within such a field. By contrast, the field of relationships between the federal government and persons who are subject to regulation by it—and, more particularly, the field of submissions made by such persons to a federal agency—is not one "which the States have traditionally occupied." *Ibid.* Like issues concerning the relationship of the United States with its contractors and employees, the duties of persons in connection with their submission of applications to a federal agency for benefits or regulatory approval involve "uniquely federal interests" that "warran[t] the displacement of state law." See *Boyle* v. *United Techs. Corp.*, 487 U.S. 500, 504-505 (1988). Those "uniquely federal interests" remain predominant when questions concerning that relationship are raised, as here, in private civil litigation. Compare *id.* at 506-507. Thus, duties concerning the submission of information to a federal agency are, at least as a general matter, appropriately defined and enforced by the federal government. See also *Pennsylvania* v. *Nelson*, 350 U.S. 497, 505 (1956) (state laws criminalizing sedition against the United States, the subject of federal legislation, are preempted because sedition is "not a *local* offense," but is a "crime against the

Nation," and thus "prosecutions should be exclusively within the control of the Federal Government") (internal quotations omitted). Cf. *Hancock* v. *Train*, 426 U.S. 167, 178-179 (1976); *Mayo* v. *United States*, 319 U.S. 441, 445-446 (1943).

There is no occasion in this case to decide, however, whether federal law completely occupies the field of submissions made by or on behalf of regulated parties to a federal agency, either generally or specifically with respect to the FDA. That is so because the premise of respondents' state-law cause of action is that particular agency action should not and would not have been taken by a federal agency, and that damages should be awarded as if the conduct of petitioner that the FDA had *cleared* under the FDCA—introducing the product onto the market—was *unlawful* under the FDCA. A state court may not decline to give effect to an FDA decision that has not been rescinded by the FDA or set aside by a court. Cf. *Nantahala Power & Light Co.* v. *Thornburg*, 476 U.S. 953 (1986); *Chicago & North Western Transp. Co.* v. *Kalo Brick & Tile Co.*, 450 U.S. 311 (1981). The federal government has a significant interest in the finality of its own administrative determinations, and under the Supremacy Clause those determinations should generally be questioned or set aside, if at all, only by the federal government itself. See, *e.g.*, *Lewis* v. *Brunswick Corp.*, 107 F.3d 1494, 1505 (11th Cir. 1997), cert. dismissed, 523 U.S. 1123 (1998).

A contrary rule could produce undesirable practical consequences. In the absence of an applicable privilege, see generally *NLRB* v. *Sears, Roebuck & Co.*, 421 U.S. 132, 150-151 (1975), "fraud on the agency" claims could subject federal agencies to countless, highly intrusive inquiries into their internal deliberations. For example, respondents assert, as necessary elements of liability, that the FDA "was ignorant" of the true intended use of the device in question; that the FDA "reli[ed]" on petitioner's misrepresentation about that intended use; and that the FDA "would not have issued

§ 510(k) clearances" for the device in the absence of petitioner's alleged fraud. Pet. App. 8a-9a.

In litigating those issues, the parties would undoubtedly seek discovery from the FDA concerning agency officials' states of mind and the hypothetical courses of action that agency decisionmakers might have taken under various counterfactual scenarios. It is the position of the United States that its employees are immune from third-party subpoenas issued in private litigation, that testimony must be sought under an agency's *Touhy* regulations, see generally *United States ex rel. Touhy* v. *Ragen*, 340 U.S. 462 (1951), and that an agency's denial of a request for testimony by agency employees is subject to review only under the "arbitrary and capricious" standard of the Administrative Procedure Act, 5 U.S.C. 706(2)(A). The lower federal courts have, however, taken divergent views on that question. Compare, *e.g.*, *Comsat Corp.* v. *National Science Found.*, 190 F.3d 269, 277-278 (4th Cir. 1999) (applying APA standard), with *Exxon Shipping Co.* v. *United States Dep't of the Interior*, 34 F.3d 774, 778-780 (9th Cir. 1994) (agency must produce evidence in response to subpoena, subject only to court's discretion to limit discovery under Fed. R. Civ. P. 26 and 45). And, in any event, widespread litigation could be expected on whether testimony and other evidence could be secured from the FDA and other federal regulatory agencies in cases such as this; this multidistrict litigation alone involves thousands of plaintiffs in more than 2000 cases that could be tried in several dozen different judicial districts. The prospect of such intrusive inquiries and attendant litigation would pose a significant potential for diverting an agency's resources and for distorting its internal decisionmaking processes.[8]

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[8] We have pointed to similar concerns in suggesting, in response to the Court's invitation in *Armstrong Surgical Ctr.* v. *Armstrong Cty. Mem. Hosp.* (No. 99-905), that there is reason for caution in fashioning any

Permitting state law suits for fraud on a federal agency could also distort the behavior of regulated entities. If a regulated entity knows that a jury applying the tort law of one of 50 States will play a central role in interpreting the entity's duties to the federal government, that concern would cause it to alter its behavior in unpredictable ways that may well be inconsistent with the efficient administration of the federal regulatory scheme.

2. The petition for certiorari should be granted. As the court of appeals acknowledged (Pet. App. 17a n.5), its decision squarely conflicts with *Mitchell* v. *Collagen Corp.*, 126 F.3d 902 (7th Cir. 1997) (*Mitchell II*), cert. denied, 523 U.S. 1020 (1998), in which the Seventh Circuit held that, despite *Medtronic*, the MDA preempts claims of "fraud through * * * representations to the FDA during the PMA process." *Id.* at 914; see also *Lewis*, 107 F.3d at 1505 (finding analogous fraud-on-the-agency claim preempted under Boat Safety Act). We agree with petitioner (see Reply Br. 3-4) that the Seventh Circuit would be bound to follow that precedent today, even though the abbreviated analysis in *Mitchell II* placed some reliance on a prior Third Circuit decision overruled by the decision below. We also agree with petitioner (see Reply Br. 4 n.2) that the decision below squarely conflicts with *Mitchell II* even though the latter

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theory of federal antitrust liability that would allow a plaintiff to recover damages from a private defendant for competitive injuries most directly caused by state administrative or adjudicatory action. 99-905 U.S. Br. at 16-18. At the same time, however, other circumstances counsel caution in concluding that claims like that in *Armstrong* may *never* be meritorious: antitrust claims are made within a well-developed legal framework, and are based on a federal statute that specifically prohibits concerted private conduct in restraint of trade, quite apart from any involvement by government actors. Those circumstances are not present in this case. Furthermore, antitrust cases, unlike this case, raise no question under the Supremacy Clause; and, unlike in this case, any conflict in the circuits on the question presented in *Armstrong* is not current or well-defined enough to require immediate review. See 99-905 U.S. Br. at 14-16, 20.

decision involved the PMA process and this case involves the Section 510(k) process. Finally, we agree that the subject-matter of the conflict is sufficiently important to warrant this Court's review; if other courts were to follow the Third Circuit's lead and permit state-law suits in this context, the result could be an unwelcome proliferation of similar claims asserting fraud on a variety of federal agencies.

To be sure, this particlar case arrives here in an interlocutory posture. The court of appeals remanded respondents' individual claims for trial, at which it would be determined, among other things, whether "the state law of fraudulent misrepresentation applicable in one or more of these cases would impose liability on [petitioner] in the circumstances alleged." Pet. App. 25a. Because the court of appeals "d[id] not hold that any of the plaintiffs have stated a claim under state law upon which relief could be granted" (*id.* at 24a-25a), it is theoretically possible that, on remand, petitioner could prevail in every case on state law grounds. Nonetheless, the court of appeals concluded (*id.* at 19a-24a) that respondents' claims against petitioner have a plausible basis in common law tort principles, and we agree with respondents (Br. in Opp. 10 n.6) that those claims might well be cognizable under the law of at least some States.[9] In our

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[9] See, *e.g.*, *Learjet Corp.* v. *Spenlinhauer*, 901 F.2d 198, 201 (1st Cir. 1990) ("[i]f, as [plaintiff] alleges, the [Federal Aviation Administration] relied on Learjet's fraudulent misrepresentations when it certified the [airplane model], and [plaintiff] purchased the [airplane] in reliance on the FAA's certification, then he has indirectly relied on Learjet's fraudulent misrepresentations" and has stated a cause of action under Kansas law); *Stanton by Brooks* v. *Astra Pharm. Prods., Inc.*, 718 F.2d 553, 569 (3d Cir. 1983) (recognizing state-law cause of action for negligent failure to file certain reports with the FDA, where, but for that negligence, the FDA "would have required notice to the medical community" of certain drug risks and "physicians receiving this information would have considered it" in deciding whether and how to administer the drug); *Hawkins* v. *Upjohn Co.*, 890 F. Supp. 609, 612 (E.D. Tex. 1994) (recognizing state-law cause of action for fraud where "[p]laintiffs assert that the FDA relied on defendants' representations in permitting the distribution of the drugs in

view, this Court therefore should grant certiorari now to decide whether such claims are foreclosed by federal law, rather than after years of what is very likely to be burdensome litigation under this and other federal statutory schemes—including numerous individual cases in numerous district courts with respect to pedicle screws alone.

CONCLUSION

The petition for writ of certiorari should be granted.

Respectfully submitted.

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question * * * and that plaintiffs[] relied on the FDA's assessment as to the drugs' safety in choosing to use the drugs"); see also *Connelly* v. *Iolab Corp.*, 927 S.W.2d 843, 855 (Mo. 1996), cert. dismissed, 520 U.S. 1260 (1997); *Green* v. *Dolsky*, 685 A.2d 110, 117 n.7 (Pa. 1996), cert. denied, 520 U.S. 1168, 1212 (1997). But cf. *Sebago, Inc.* v. *Beazer East, Inc.*, 18 F. Supp. 2d 70, 86-88 (D. Mass 1998).

(19)

No. 98-1768

Supreme Court, U.S.
FILED
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In the Supreme Court of the United States

THE BUCKMAN COMPANY,
Petitioner,

v.

PLAINTIFFS' LEGAL COMMITTEE,
Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Third Circuit

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RELEVANT DOCKET ENTRIES

August 8, 1994	Order of the Judicial Panel on Multidistrict Litigation entered transferring individual actions to Eastern District of Pennsylvania for coordinated or consolidated pretrial proceedings
Oct. 25, 1994	Motion to dismiss for failure to state a claim filed by AcroMed Corporation
Jan. 23, 1995	Motion to dismiss for failure to state a claim and for lack of subject matter and personal jurisdiction filed by Arthur Steffee and Edward Wagner
Feb. 13, 1995	Motions to dismiss for failure to state a claim filed by AcroMed Corporation
March 2, 1995	Memorandum and Pretrial Order No. 12 entered granting motions for partial judgment on the pleadings filed by AcroMed Corporation, Arthur Steffee and Edward Wagner
April 17, 1995	Motion for summary judgment or partial summary judgment on the grounds of preemption or deference to agency expertise filed by AcroMed Corporation
Oct. 31, 1996	Motion to reaffirm Pretrial Order No. 12 in light of *Medtronic, Inc.* v. *Lohr* filed by AcroMed Corporation
Nov. 1, 1996	Joinder by Buckman Company in AcroMed's motion to reaffirm Pretrial Order No. 12 in light of *Medtronic, Inc.* v. *Lohr*

Dec. 2. 1996	Motion to dismiss amended omni complaint for failure to state a claim upon which relief may be granted filed by Buckman Company
March 28, 1997	Memorandum and Pretrial Order No. 845 entered granting in part motion to reaffirm Pretrial Order No. 12 in light of *Medtronic, Inc.* v. *Lohr*
April 7, 1997	Motion for certification of immediate interlocutory appeal under 28 U.S.C. § 1292(b) of issues decided in Pretrial Order No. 845 filed by Plaintiffs' Legal Committee
May 12, 1997	Pretrial Order No. 900 entered granting Buckman Company's motion to dismiss amended omni complaint for failure to state a claim upon which relief may be granted
Sept. 12, 1997	Pretrial order no. 1067 entered directing entry of final judgment under Fed. R. Civ. P. 54(b) in favor of Buckman Company on plaintiffs' fraud-on-the-FDA claims in the amended omni complaints and dismissing Buckman Company from litigation
Nov. 17, 1998	Opinion and judgment by the U.S. Court of Appeals for the Third Circuit entered reversing judgment of district court and remanding for further proceedings
June 29, 2000	Order of the Supreme Court of the United States entered granting Buckman Company's petition for a writ of certiorari

RELEVANT DOCKET ENTRIES NOT INCLUDED

The following opinions, decisions, judgments, and orders have been omitted in printing this joint appendix because they appear at the pages indicated in the appendix to the Petition for a Writ of Certiorari:

Memorandum Opinion and Pretrial Order No. 12 of the United States District Court for the Eastern District of Pennsylvania, dated March 2, 1995 ..... 46a

Memorandum Opinion and Pretrial Order No. 845 of the United States District Court for the Eastern District of Pennsylvania, dated March 28, 1997 ..... 33a

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IN THE SUPREME COURT OF THE UNITED STATES

Buckman Company, Petitioner
v.
Plaintiffs' Legal Committee, Respondent.
No. 98-1768

June 29, 2000

Motion of Medical Device Manufacturers Association for leave to file a brief as amicus curiae granted. Motion of Danek Medical, Inc., for leave to file a brief as amicus curiae granted. Motion of Product Liability Advisory Council, Inc., for leave to file a brief as amicus curiae granted. Motion of Pharmaceutical Research and Manufacturers of America for leave to file a brief as amicus curiae granted. Petition for writ of certiorari to the United States Court of Appeals for the Third Circuit granted limited to the following question: Whether federal law preempts state-law tort claims alleging fraud on the Food and Drug Administration during the regulatory process for marketing clearance applicable to certain medical devices.

IN THE UNITED STATES DISTRICT COURT
JUDICIAL DISTRICT OF ALASKA

Donald G. Patterson, and Linda A. Patterson, Plaintiff,
v.
AcroMed Corporation, Charter No. 614043; AcroMed Corp. (Now AcroMed Corporation, Charter No. 614043); AcroMed Corporation, Charter No. 816942; AcroMed Inc., Charter No. 811415); AcroMed Incorporated, Charter No. 816943; AcroMed Holding Corporation, Charter No. 811416); AcroMed Corporation (now AcroMed Holding Corporation, Charter No. 811416); Horizon Orthopedic, Inc., f/k/a Steffee Orthopedic, Inc., f/k/a Arthur D. Steffee, MD., Inc.; Arthur D. Steffee; William C. Carson; Isola Implants, Inc.; Behrooz Akbarnia; Marc Asher; Robert Biscup; John Brantigan; Mark Brown; Samuel Chewning; Sanford Davne; Robert Gaines; Brad Hall; Charles Heinig; Louis Keppler; Mark Lorenz; Paul C. McAfee; Donald Myers; Theodore Wagner; James Weinstein; Michael Zindrick; American Academy of Orthopaedic Surgeons; North American Spine Society; Scoliosis Research Society; American Association of Neurological Surgeons; Buckman Company, Inc.; Ace Medical Company; Advanced Spine Fixation Systems, Inc.; Cross Medical Products, Inc.; Danek Medical, Inc.; Sofamore, Inc.; Sofamor-Danek Group, Inc.; Sofamore, S.N.C.; DePuy-Motech, Inc.; Scientific Spinal; Smith & Nephew Richards, Inc.; Synthes (U.S.A.); Synthes, Inc.; Synthes North American, Inc.; Synthes, A.G. Chur; Youngwood Medical Specialities, Inc., f/k/a National Medical Speciality, Inc., f/k/a Stuart Medical Speciality, Inc.; Zimmer, Inc., Defendants.

CIVIL ACTION NO. A96 465 CIV (HRH)
EDPA 97-1488
JURY TRIAL DEMANDED

COMPLAINT
Filed Dec. 2, 1996

* * * General Statement of Facts and Regulatory Background

46. AcroMed designed, manufactured, and then unlawfully promoted, marketed, distributed and sold a variety of pedicle screw fixation devices for surgical implantation into the spine, including the device implanted in Plaintiff's spine.

47. Others, including Ace Medical Company ("Ace"), Advanced Spine Fixation Systems, Inc. ("ASFSI"), Cross Medical Products, Inc. ("Cross"), Danek Medical, Inc. ("Danek"), Sofamor, Sofamor-Danek Group, Inc. ("Sofamor-Danek"), DePuy-Motech, Inc. ("DePuy"), Scientific Spinal, Smith & Nephew Richards, Inc. ("SNR"), Synthes and Zimmer, Inc. ("Zimmer"), designed, manufactured, and then unlawfully promoted, marketed, distributed and sold a variety of pedicle screw fixation devices for surgical implantation into the spine.

48. AcroMed's pedicle screw fixation devices were and are known as the Nested Bone Plate; Cancellous Bone Screw; Variable Screw Placement ("VSP") Spinal Fixation System; Titanium VSP Bone Plates and Bone Screws; and ISOLA System, all of which are medical devices that are regulated by the Food and Drug Administration ("FDA") and governed by the Food, Drug and Cosmetic Act ("FDCA") and the Medical Device Amendments ("MDAs") thereto.

49. Pedicle screw fixation devices were designed and intended to be used in spinal fusion surgery in which surgical techniques are applied to cause two or more vertebrae to fuse together in order to correct various conditions involving spinal instability or deformity. Generally, these devices consist of components such as plates or rods which are attached posteriorly along the vertical axis of the spine with screws inserted into the vertebral pedicles.

50. Pedicle screw fixation devices have been classified by the FDA as Class III devices which "present a potential unreasonable risk of illness or injury" and therefore must receive premarket approval from the FDA before they may be commercially distributed or sold.

51. The FDA may not grant premarket approval for a Class III device unless it determines that there is "reasonable assurance that such device is safe and effective under the conditions of use prescribed recommended or suggested in the proposed labeling thereof."

52. An applicant for premarket approval must furnish the FDA with safety and efficacy data from non-clinical laboratory studies and controlled prospective studies conducted in accordance with protocols approved by the FDA.

53. If a manufacturer wishes to generate the scientific data necessary to obtain premarket approval and thereby market a Class III medical device, it may do so only under the Investigational Device Exemption ("IDE") provisions of the MDAs, which permit experimental devices to be used in humans, without premarket approval, under stringent conditions established and actively supervised by the FDA.

54. When the FDA grants an IDE for a Class III medical device, the device is considered an "investigational device" only. Therefore, under the FDA regulations "the IDE sponsor, the IDE investigator, or any person acting for or on behalf of a sponsor or investigator" may not "promote or test market an investigational device, until after the FDA has approved the device for commercial distribution." Moreover, under the FDA regulations "the IDE sponsor, investigator, or any person acting for or on behalf of a sponsor or investigator" may not "represent that an investigational device is safe or effective for the purposes for which it is being investigated."

55. All devices which were in commerce prior to the effective date of the MDA, May 28, 1976, may remain in commerce without further regulatory action by the FDA.

56. Devices not in commerce prior to May 28, 1976 are presumptively Class III devices and may not be introduced into commerce without premarket approval unless:

(a) the new device is reclassified into Class I or Class II by the FDA in response to a reclassification petition, or

(b) the FDA determines that the device is "substantially equivalent" to a "predicate device," which is a device that was in commerce prior to May 28, 1976 or that was introduced thereafter and was reclassified as a Class I or Class II device.

57. In the event a marketer of a new medical device claims the device is substantially equivalent to a predicate device, it must submit a premarket ("510(k)") notification to the FDA advising the agency of its intent to market the new medical device. In response to such a notification, the FDA will determine whether the device is substantially equivalent to a predicate device. An FDA determination of substantial equivalence is colloquially known as "510(k) clearance."

58. A new device is not "substantially equivalent" to a predicate device unless the device has the same intended use as a predicate device.

59. The FDA defines "intended use" in relation to the labeling of medical devices as:

> [T]he objective intent of the persons legally responsible for the labeling of devices. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives.

60. Different intended uses for the same physical apparatus give rise to different devices, each of which must receive premarket approval or clearance by the FDA pursuant to a 510(k) notification.

61. Thus, it is unlawful for any person to market, sell, or otherwise introduce into commerce a new Class III medical device for an intended use unless it has received premarket approval or 510(k) clearance for that intended use.

62. Under the FDCA, the "following acts and the causing thereof" are prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any...device...that is adulterated or misbranded;

(b) The adulteration or misbranding of any...device...in interstate commerce;

(c) The receipt in interstate commerce of any...device... that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise. 21 *U.S.C.* § 331.

63. Violation of these prohibitions is a crime. 21 *U.S.C.* §333.

64. Under the FDCA, "a...device shall be deemed to be adulterated" with respect to an intended use if it is a Class III device which has not received premarket approval or 510(k) clearance with respect to that intended use. *See* 21 *U. S. C.* §351(f).

65. The FDCA expressly provides that "a ...device shall be deemed to be adulterated...if it is a device for which [an investigational device] exemption has been granted...and the person who was granted such exemption or any investigator who uses such device under such exemption fails to comply with a requirement prescribed by [the FDA]." 21 *U.S.C.* §351(i). This means that a device is adulterated if an IDE sponsor, an IDE investigator, or any person acting for or on behalf of a sponsor or investigator promotes a device for an investigational use or represents that an investigational device is safe or effective for the purposes for which it is being investigated in violation of the FDA's regulations governing IDEs. 21 *C.F.R.* §812.7(a) and (d).

66. The FDCA provides that "a...device shall be deemed to be misbranded" unless its labeling bears "adequate directions" for the intended use of the device including indications, effects, relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the device can use the device safely and for the purposes for which it is intended. *See* 21 U.S.C. §352(f) and 21 *C.F.R.* §§801.4 and 801.109.

67. Prior to 1984, pedicle screw fixation devices were not available or used in the United States.

68. In 1984, AcroMed filed a 510(k) notification seeking permission from the FDA to market a pedicle screw fixation system. Thereafter, other manufacturers and sellers of pedicle screw fixation devices likewise sought clearance from the FDA to market their devices.

69. These new devices, including AcroMed's devices, were of questionable efficacy in comparison to existing methodologies of treatment and presented the following serious potential risks, among others, not posed by existing spine fusion technology:

(a) The relatively small diameter, together with the unpredictable, highly variable and irregular size, contour and spatial orientation of the pedicles of the spine, and the relatively large outer diameter of the pedicle screws make it extremely difficult for even the most experienced and technically capable surgeon to place the screws entirely within the pedicles without having some portion of the screw breach the external walls of the bone.

(b) Placement of pedicle screws may compress a nerve root, the spinal cord, the sinuvertebral nerves, or the nerves in the sympathetic chain, causing irreversible, permanent nerve and tissue damage. Nerve root irritation resulting from malposed pedicle screws may also produce nerve root irritation which results in ill-defined lower extremity symptoms, including pain, without well-defined neurologic deficit.

(c) Mechanical device failures, caused by repeated application of stress to the metallic elements employed within the internal pedicle screw fixation construct due to motion between the vertebrae sought to be fused can result in stress fractures of the mechanical elements, bending of those elements or loosening and pulling out of the pedicle screws, pseudarthrosis or lack of fusion, and injury to the

spinal cord, cauda equina and nerve roots which lie in close proximity to the device elements.

(d) The presence of the devices may cause diminution in bone density, or osteoporosis, which occurs through the biomechanical process known as "stress shielding." This diminution in bone density, in turn, decreases the "purchase" or holding power of the pedicle screws and/or the bone quality of the fusion mass, producing an increased risk of late screw migration, nerve damage and pseudarthrosis.

(e) Pedicle screws create an increased risk of inflammation and fibrosis due to the presence of a foreign material in the body. In addition, the components of pedicle screw fixation devices abrade against each other, causing metal fretting that often produces significant quantities of corrosion products and a severe inflammatory response.

(f) Insertion of pedicle screws and attachment of plates or rods may cause pedicular fracture or pedicular microfracture which is difficult to diagnose post-surgically. The bleeding associated with such fractures adds to scarring and pedicular bulk.

(g) The shape, location, contour and bulk of pedicular hardware causes chronic irritation to the overlying paraspinal muscles producing chronic pain.

(h) The placement of pedicular fixation hardware may destabilize the spine and interfere with the fusion process.

(i) Positioning of the screw in the pedicle may block normal venous channels within the bone leading to increased venous pressure with possible concomitant engorgement or alteration in blood flow, necrosis and injury to surrounding tissues.

(j) Pedicle screw devices create an increased risk of infection. Spinal infections are associated with increased rates of epidural scarring which, in turn, results in the tethering and

compression of nerves and nerve roots which causes disabling pain and dysfunction.

70. Because pedicle screw fixation systems represented a new post-amendment technology which presented health risks not engendered by other spinal fixation systems, the FDA consistently refused to clear any of these devices for market under the 510(k) substantial equivalency process.

71. Beginning in 1984 and continuing through January of 1995, the FDA determined that all spinal fixation systems incorporating pedicle screws were not substantially equivalent to any legally marketed predicate device and were new Class III devices which required premarket approval from the FDA before they could be introduced or delivered for introduction into interstate commerce.

72. In order to permit AcroMed and other manufacturers of such devices to generate scientific evidence necessary to obtain premarket approval, the FDA granted approval to conduct fourteen separate IDE clinical trials for various pedicle screw fixation devices during the period from 1986 through 1993. Each of the pedicle screw fixation devices manufactured by AcroMed was the subject of an IDE.

73. None of these IDEs generated sufficient evidence of safety and efficacy of pedicle screw fixation devices to support a successful application for premarket approval.

74. Accordingly, at all times material to this Complaint it was illegal to sell any device intended as a pedicle screw fixation system or to market or promote any medical device for use with screws inserted posteriorly into the spinal pedicles (apart from devices used in the FDA-approved IDE trials).

75. Notwithstanding this legal prohibition, AcroMed promoted, marketed, distributed, and sold devices which were intended for use as pedicle screw fixation devices on a massive scale outside of any approved IDE in violation of the prohibitions of federal law against adulteration and misbranding.

76. In addition, the remaining Defendants also participated in the promotion, marketing, distribution and sale of devices which were intended for use as pedicle screw fixation devices on a massive scale outside of any approved IDE in violation of the prohibitions of federal law against adulteration and misbranding.

77. As a result, hundreds of thousands of patients, including Plaintiff, were surgically implanted with spinal fixation devices within the pedicles of their spine even though there was inadequate evidence to provide a reasonable assurance that such devices were safe and effective when used in that. manner.

Count 1: Fraud (on the FDA)

78. Plaintiff realleges each and every allegation set forth in the Paragraphs above and farther alleges as follows:

79. The claims made in this Count of the Complaint are brought by Plaintiff against AcroMed, Steffee, and Buckman.

80. Arthur D. Steffee ('Steffee") formed AcroMed in 1983 in order to manufacture and sell orthopedic devices and specifically pedicle screw implants and instrumentation.

81. Steffee has remained the controlling shareholder in AcroMed and a member of its Board of Directors from the inception of the company through the present.

82. In 1983, Steffee developed the VSP spinal plate fixation system for use solely in spinal fusion surgery and not for repairing fractures in bones outside of the spine. The device consisted of slotted plates which were intended to be attached along the vertical access of the spine with screws inserted posteriorly into the spinal pedicles.

83. AcroMed began selling the VSP device in interstate commerce in early 1984 without filing a Section 510(k) premarket notification as required by federal law.

84. On September 4, 1984, AcroMed sought to cure this violation by filing a 510(k) premarket notification for the VSP device. This notification represented accurately that the device was intended for use in spinal surgery.

85. On December 19, 1984, the FDA determined that the VSP device was a Class III device which was not substantially equivalent to any device marketed in interstate commerce prior to May 28, 1976 and therefore could not be commercially distributed without premarket approval.

86. Thereafter, AcroMed continued to commercially distribute its VSP system without applying for or obtaining premarket approval.

87. In March of 1985, AcroMed met with Carl Larson at the FDA and was told that the clinical data which AcroMed had submitted in its premarket notification were suspect and insufficient in that they came only from Steffee who had a financial interest in the commercial exploitation of the device and they revealed a twenty percent (20%) device failure rate, and, therefore, the FDA could not make a determination concerning the device's safety and effectiveness.

88. Thereafter, AcroMed filed another 510(k) premarket notification on September 20, 1985, supplying the FDA with additional data. This notification again accurately stated that the device was intended for us in spinal fixation surgery.

89. In response to this 510(k) notification the FDA again determined that the device was not substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976 and posed potential risks not exhibited by other spinal fixation systems, and, therefore, the VSP device was a Class III device which could not be legally marketed without premarket approval.

90. Determined to "immediately sell the VSP system for spinal fixation," AcroMed hired Buckman Company, Inc. ("Buckman"), and together with Steffee, they concocted and agreed to an unlawful and deceptive scheme in the fall of 1985 to bring the VSP spine plate fixation device to market without premarket approval and without the development of the kind of safety and efficacy data necessary to obtain such premarket approval.

91. The unlawful plan contemplated that:

(a) AcroMed would fraudulently seek 510(k) clearance of the components of the VSP system as bone plates and bone screws to be used in repairing fractures of the long bones, even though the sole intended use of these components was as an assembled spine plate/pedicle screw fixation system;

(b) Once clearance from the FDA had been obtained, AcroMed would contend that "FDA's determination of substantial equivalence constitutes official notification from the FDA that the devices are safe and effective and that such devices may be introduced commercially for medical use";

(c) Consistent with AcroMed's goal to sell the VSP device in interstate commerce, AcroMed would promote the cleared device components for use solely in spinal applications by using physicians such as Steffee to train other physicians in spinal applications of the device components as a spine plate/pedicle screw fixation system.

92. In accordance with this plan to deceive the FDA and ultimately the public in order to obtain 510(k) clearance for the VSP device, AcroMed changed the name of the VSP device from a "spinal plate fixation system" to "nested bone plates" and "cancellous bone screws."

93. On December 20 and December 30, 1985, respectively, AcroMed submitted two separate 510(k) premarket notifications to the FDA for the plate and screw components of the VSP system, omitting all references to the use of the device in the spine and falsely representing to the FDA that the device components were substantially equivalent to pre-amendment Class II devices used in the repair of fractures of the long bones of the arms and legs.

94. In response to the FDA's inquiry concerning the intended use of the bone plates and bone screws, on January 10, 1986, Buckman, acting as a representative for AcroMed and with AcroMed's knowledge, intentionally and falsely represented to the FDA

that "[t]he proposed indications for use for the AcroMed device are the same general indications proposed for the AO system of plates...[and] are intended for use in appropriate fractures of long bones of both the upper and lower extremity and such other flat bones (as in the fractured pelvis)."

95. AcroMed, Buckman and Steffee intended for the FDA to clear the VSP device components based upon this misrepresentation.

96. In reliance on this express misrepresentation, the FDA determined in January, 1986 that AcroMed's nested bone plates and cancellous bone screws were substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976 for the intended use represented by AcroMed.

97. AcroMed's president, Ed Wagner, admitted in a letter which he wrote on January 16, 1986 that this representation to the FDA was false — that AcroMed sought approval of its VSP plates and screws for use in the long bones simply as a pretext in order to market the device for its true intended use in the spine.

98. In addition, AcroMed's Vice President and Chief Counsel, Geoffrey Porter, admitted under oath that the **only purpose** for which AcroMed's plates and screws were sold was for use in the spine.

99. Steffee also has admitted that the VSP device was intended exclusively for use in the spine and not as a general orthopedic implant.

100. In January of 1986, AcroMed applied for an IDE to conduct clinical trials of the VSP device in the human spine. In its IDE application, AcroMed acknowledged to the FDA that spinal application of the VSP device was "experimental" and affirmatively represented that the device would not be employed in spinal procedures on any patients other than the 250 patients participating in the IDE study.

101. Nevertheless, AcroMed marketed and promoted the VSP device on a massive basis outside of its IDE trial solely for that prohibited use.

102. Due to serious problems with the VSP IDE trials, the FDA, in April of 1990, withdrew approval of AcroMed's IDE because according to the FDA "continuing of testing under the exemption [would] result in an unreasonable risk to the public health," and "the rights, safety and welfare of the patients in this investigation [were] not being protected and there [was] reason to believe that the scientific soundness of this investigation [had] been compromised."

103. On November 30, 1987, AcroMed submitted a 510(k) notification to the FDA with respect to an "integral nut" screw which was a revised version of the cancellous bone screw for which AcroMed had received 510(k) clearance in January, 1986.

104. In the 510(k) notification which AcroMed submitted for the integral nut screw, AcroMed knowingly and falsely represented to the FDA that the screw was intended for general orthopedic applications and not intended for use in the pedicles of the spine.

105. This representation was false.

106. Indeed, at the time AcroMed made this representation, AcroMed intended that the integral nut screw be used in the pedicles of the spine as a point of attachment for both AcroMed's VSP bone plates and the rods of the ISOLA spine fixation system which it had been developing.

107. AcroMed intended that the FDA clear this screw for marketing based on AcroMed's 510(k) submission.

108. As a result of and in reliance on these misrepresentations to the FDA concerning the intended use of AcroMed's integral nut screw, the FDA issued a 510(k) clearance for non-pedicle uses of the bone screw on January 20, 1988.

109. Beginning in 1985 and continuing through 1990, Marc Asher ("Asher"), together with William C. Carson ("Carson") and Charles Heinig ("Heinig"), shareholders in ISOLA Implants, Inc., developed the ISOLA Spine Fixation System, to serve as a spinal

fixation device using rods and VSP pedicle screws generally as well as hooks for certain limited indications.

110. AcroMed employed Buckman to assist it in successfully bringing ISOLA to market, using the same fraudulent scheme they had used with the VSP device.

111. Specifically, on June 27, 1988, Buckman, on behalf of AcroMed, submitted an IDE application for ISOLA to the FDA which admitted that the "ISOLA Spine System uses pedicle screws as the point of fixation."

112. Shortly thereafter, on September 29, 1988, Buckman submitted three separate 510(k) premarket notifications for components of the ISOLA system: the "iliac screw, the Eye Rod, and spinal rod and hooks."

113. None of these premarket notifications admitted that the device components were to be used in connection with pedicular fixation, but instead falsely claimed substantial equivalence to fixation devices used for attachment to the spine with hooks or with screws inserted in locations other than the pedicles of the spine.

114. In response to the FDA's expressed desire to combine the three 510(k)s so it could ask questions about the components as an entire system, Buckman advised AcroMed that "it is to Acro-Med's advantage to get each component approved separately. By maintaining the individual 510(k)'s, we can assert that any system questions are not relevant...," and "the trick will be in convincing the FDA that the components are not a system and therefore should be evaluated individually."

115. In accordance with AcroMed's plan to deceive the FDA and ultimately the public, AcroMed and Buckman submitted three separate false and/or deceptive responses to the FDA, each answering those questions that applied to the related device component submissions.

116. For example, Buckman claimed falsely that since the iliac screw was to be marketed separately, "[i]ts substantial

equivalence should be determined as an individual device not as a component part...."

117. AcroMed and Buckman intended that the FDA clear the components of the ISOLA system based on the 510(k) submissions.

118. In reliance on AcroMed and Buckman's express misrepresentations, on April 26, 1989, the FDA granted 510(k) marketing clearance for the ISOLA spinal rods and hooks, and on May 3, 1989, the FDA granted 510(k) clearance for the iliac screw.

119. The FDA informed AcroMed that the iliac screw "may not be labeled or promoted for pedicular attachment to, or fixation of, the spine," and "all labeling for this device, including package label and labeling included within the package, must prominently state that the screws of this device are intended for sacral/iliac attachment only" and labeling must include the statement: "WARNING - THIS DEVICE HAS NOT BEEN APPROVED FOR PEDICULAR APPLICATION."

120. In furtherance of their unlawful plan to market pedicle screw fixation devices, in the early part of 1990, AcroMed, ISOLA Implants, Inc. and Asher made certain changes to the components of the ISOLA system creating slotted connectors for the specific purpose of permitting a surgeon to connect ISOLA rods to VSP screws inserted in the spinal pedicles.

121. On January 27 and December 28, 1990, AcroMed submitted 510(k) notifications for the ISOLA slotted connectors, in which it knowingly made a false representation that "the connectors are for use when the stabilization of the spine requires anchoring through the ilium/sacrum," and in which it falsely disclaimed any intended use in connection with pedicle screws.

122. On March 14, 1991, AcroMed knowingly made a false representation to the FDA that the slotted connectors were intended to be used only with the components of the ISOLA system, and not with any other system including the bone screws developed for pedicular attachment to the VSP system.

123. AcroMed intended that the FDA clear these slotted connectors for marketing based upon these 510(k) submissions and AcroMed's misrepresentations concerning the intended use of the slotted connectors.

124. In reliance on AcroMed's misrepresentations, the FDA issued a 510(k) clearance for the ISOLA slotted connectors on March 21, 1991, which expressly stated that if AcroMed labeled or promoted the devices for pedicle screw fixation, the devices would be adulterated in violation of federal law.

125. AcroMed's and Buckman's representations to the FDA with regard to the intended use of the ISOLA system and its components were plainly false and misleading.

126. Asher conceded that the ISOLA system was a pedicle screw system designed and developed for use with AcroMed's VSP pedicle screws.

127. Indeed, Asher developed a technique manual, a videotape, and a distributor notebook, all of which demonstrated pedicle screw fixation with the ISOLA device and each of which was customarily provided to surgeons and/or distributors in the United States.

128. In addition, AcroMed and Isola Implants, Inc. entered into a royalty arrangement expressly contemplating payment of a royalty on "sales of AcroMed integral nut pedicle screws" for use with the ISOLA system both within the limited ISOLA IDE and for "commercial sales" outside of the ISOLA IDE.

129. Consistent with the intention that the ISOLA system be used for pedicular attachment to the spine with VSP screws, AcroMed actively marketed, promoted, distributed, and sold the device for that purpose on a massive basis outside of the ISOLA IDE.

130. The misrepresentations by AcroMed, Steffee, and Buckman as described in Count I of this Complaint were made intentionally to deceive the FDA and to induce it to issue 510(k) clearances for the VSP and ISOLA devices and device components

in order to provide a pretext to claim that the devices could be lawfully introduced in interstate commerce.

131. The FDA was ignorant of the fact that these devices and device components were intended by AcroMed to be used as pedicle screw fixation devices.

132. Were it not for these fraudulent acts and statements, the FDA would not have issued 510(k) clearances for AcroMed's pedicle screw fixation devices for any purpose, the devices would not have been introduced into interstate commerce, and Plaintiff would not have been exposed to the dangerous device which was surgically implanted in the Plaintiff's spine.

133. The FDA, Plaintiff and Plaintiff's implanting physician relied upon these Defendants to make truthful statements to the FDA in their 510(k) notifications regarding the intended use of the device at issue so that Plaintiff would not be implanted with a defective medical device that was never proven to be safe and effective for the use for which it was intended, i.e. pedicle screw fixation.

134. As a direct and proximate result of the wrongful conduct alleged in Count I of this Complaint, Plaintiff has suffered, and will continue to suffer, severe physical harm, including injury to Plaintiff's spine, spinal nerves, spinal nerve roots, and surrounding nerves, tissues, cells, and vascular structures. As a result, Plaintiff has in the past and will in the future sustain and suffer a loss of earnings, an impairment in earning capacity, severe physical pain, mental anguish, emotional distress, disability, liabilities for medical and rehabilitative expenses, and other forms of injury, loss and damage.

* * * *

IN THE UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF PENNSYLVANIA

[Caption omitted]

AcroMed's Motion for Summary Judgment or Partial Summary Judgment on the Grounds of Preemption or Deference to Agency Expertise

Filed April 17, 1995

[Text of Motion omitted]

Affidavit of William Christianson

[Text of affidavit and Exhibits 1-19 omitted]

Exhibit 20 to Affidavit of William Christianson

Department of Health and Human Services
Public Health Service
Food and Drug Administration
8757 Georgia Avenue
Silver Spring, MD

May 3, 1989

Joyce L. Bromm, R.N., J.D.
Buckman Company, Inc.
Representing AcroMed Corporation
921 Calle Verde
Martinez, California 94553

Re: K884161
AcroMed Iliac Screw
Regulatory Class: II
Dated: February 1, 1989
Received: February 2, 1989

Dear Ms. Bromm:

We have received your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. This decision is based on posterior spinal fixation/stabilization devices being equivalent only to similar devices labeled and intended to be fixed to the spine by laminar hooks and sacral/iliac attachment. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) and the following limitations:

1. This device may not be labeled or promoted for pedicular attachment to, or fixation of, the spine.

2. All labeling for this device, including package label and labeling included within the package, must prominently state that the screws of this device are intended for sacral/iliac attachment only and include the statement: "WARNING – THIS DEVICE HAS NOT BEEN APPROVED FOR PEDICULAR APPLICATION."

3. Any pedicular fixation of this device is considered investigational and may only be investigated as a significant risk device in accordance with the investigational device exemption (IDE) regulation under 21 CFR, Part 812. All users of the device for pedicular attachment/fixation must receive approval from their respective institutional review boards (IRBs) and the Food and Drug Administration (FDA) to conduct the investigation.

The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

You may market your device under the above limitations as a class II device. If you market this device with any claims or indications

other than as a posterior laminar hook attachment system, the device would be considered class III and as such it would be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

This letter will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a pre-amendments device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device please contact the Division of Compliance Operations, REgulatory Guidance Branch (HFZ-323) at (301) 427-8040. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

/s/
Carl A. Larson, Ph.D.
Director, Division of Surgical
and Rehabilitation Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

IN THE UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF PENNSYLVANIA

[Caption omitted]

Reply Memorandum To Motion By United States
Of America On Behalf Of The Food And Drug
Administration For Protective Order

Filed August 10, 1995

[Text of Reply Memorandum omitted]

EXHIBIT A
IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

[Caption omitted]

[Caption omitted]

NOTICE OF DEPOSITIONS

PLEASE TAKE NOTICE that plaintiffs in the above-entitled action will take the depositions, upon oral examination, of the following persons on the dates, at the times and in the places listed. The depositions are being taken pursuant to Paragraph 2 of Pretrial Order No. 51. At each deposition, each witness shall be required to produce those documents listed in Schedule "A" to this Notice. The depositions shall take place before a Notary Public and shall be stenographically transcribed and may also be recorded by videotape

Name of Deponent	Date and Time of Deposition	Place of Deposition
David A. Murray	* * *	
Paula Wilkerson	* * *	
Bernard F. Morrey	* * *	

Michael D. Mayor ***
Daniel R. Benson ***
Thomas Whitecloud ***
Mark Melkerson ***
William J. Kane ***
Nirmal Mishra ***
Curtis Dickman ***
Martin Yahiro ***
Alvin Crawford ***
Hansen Yuan ***
Steven Mardjerko ***
Thomas Zdeblick ***
Leela Rangaswany ***
Steven Garfin ***
Claudia Thomas Cartie ***
Seth Greenwald ***
Edward N. Hanley ***
Christine Incorvaia ***
Philip Molgren ***

By: _____
Arnold Levin
Liaison Counsel
PLAINTIFFS' LEGAL COMMITTEE

SCHEDULE "A"

I. DEFINITIONS

As used herein, the following terms have the following meanings:

1. The term "document is used in its broadest possible sense to refer to any document or other tangible matter or thing which may be properly subject to a request under the Freedom of Information Act and your implementing regulations.

2. The term "Cohort Study" refers to the historical Cohort Study of Pedicle Screw Fixation in Thoracic, Lumbar and Sacral Spine Fusions, the results of which were reported to the Orthopedic and Rehabilitation Devices Advisory Committee Panel meeting on July 22, 1994 and in the October, 1994 supplement to *Spine* magazine.

3. The term "relevant premarket notifications" refers to all premarket notifications submitted under Section 510k of the Food, Drug and Cosmetic Act at any time from January 1, 1993 through the present in which the intended use of the device was posterior attachment to the spine by means of screws inserted through the spinal pedicles.

II. DOCUMENTS REQUESTED

1. All documents reflecting, relating or referring directly or indirectly, to the Cohort Study.

2. All documents reflecting, relating or referring to each and every event involved in planning for the Cohort Study, including any plans or protocols which were abandoned or not otherwise carried out.

3. All documents reflecting, relating or referring to the implementation of any plans for the Cohort Study including transactions undertaken and ultimately not included within the study.

4. All documents reflecting, relating or referring to any results of the Cohort Study including, without limitation, results which were not reported as part of the study.

5. All documents reflecting, relating or referring to any communications among any persons including physicians, organizations of physicians, manufacturers, organizations of manufacturers, the Food and Drug Administration, the National Institute of Health, and any other person, entity or organization with regard to the Cohort Study.

6. All documents reflecting, relating, or referring, directly or indirectly, to the payment of money or any item of value to or for the benefit of any person in connection with the Cohort Study.

7. All documents reflecting, relating or referring, directly or indirectly, to clinical data solicited in connection with the Cohort Study.

8. All documents reflecting, relating or referring, directly or indirectly, to the analysis, review, audit, retention and/or destruction of any clinical data solicited or received in connection with the Cohort Study.

9. All documents reflecting, relating or referring to the identity of each and every person who was involved in any aspect of the Cohort Study.

10. All documents reflecting, relating or referring to any audit procedure which was proposed or implemented in connection with the Cohort Study.

11. All documents reflecting, relating or referring to any analysis, summary or meta-analysis of literature with regard to the subject of pedicle screw fixation which was used or proposed to be used in connection with the Cohort Study including analyses used for purposes of selecting study "controls," and meta-analyses and summaries presented or proposed to be presented to the July 22, 1994 Advisory Panel meeting.

12. All documents reflecting, relating or referring to the identity of each physician who submitted data in connection with the Cohort Study.

13. All documents reflecting, relating or referring to any transaction in which any FDA employee or consultant and/or physician and/or entity who supplied data in connection with the Cohort Study received or had a relative or entity with which he was affiliated receive money, securities, items of value or the promise of money, securities or other items of value, contingent or otherwise, from any member of the Spinal Implant Manufacturers Group.

14. All documents reflecting, relating or referring, directly or indirectly, to directions, instructions, protocols, procedures, or the like in connection with the Cohort Study.

15. All data derived from the Cohort Study in the form of computer tapes, disks, diskettes, hard drive, or other electronic storage media together with such documents as are necessary for the complete understanding of the manner in which such data have been stored and may be effectively retrieved.

16. All documents reflecting, relating or referring to each and every "control" used in connection with the Cohort Study.

17. All documents reflecting, relating or referring to the payment of money, the conveyance of anything of value or the promise of such payment or conveyance, contingent or otherwise, by any person to or for the benefit of any FDA consultant or any employee of the FDA in connection with the Cohort Study.

18. All documents reflecting, relating or referring to any communications between any employee of the FDA and/or any FDA consultant, on the one hand, and any member of the Spinal Implant Manufacturers Group, Advanced Biosearch Associates, North American Spine Society, Scoliosis Research Society and/or the American Association of Orthopedic Surgeons, on the other ha[n]d, with respect to the subject of the pedicle screw fixation and/or the regulation thereof.

19. Each of the relevant premarket notifications.

20. All documents reflecting, relating or referring to the FDA's consideration of each of the relevant premarket notifications.

21. All documents reflecting, relating or referring to any communications regarding each of the relevant premarket notifications and any agency action thereon.

22. All documents reflecting, relating or referring to each "predicate device" for which substantial equivalence was claimed in each of the relevant premarket notifications.

23. All documents reflecting, relating or referring to any communications between any employee of the FDA and/or any FDA consultant on the one hand, and any member of the Spinal Implant Manufacturers Group, Advanced Biosearch Associates, North American Spine Society, Sc[olio]sis Research Society and/or the

American Association of Orthopedic Surgeons, on the other hand, with respect to each of the relevant premarket notifications.

24. All documents reflecting, relating or referring to the payment of money or the conveyance of any thing of value to or for the benefit of any FDA employee or consultant in connection with any of the relevant premarket notifications and any agency action thereon.

25. All documents which reflect any agency action on each of the relevant premarket notifications.

26. All documents reflecting, relating or referring to the justification for any agency action taken in response to each of the relevant premarket notifications including any agency determination to "clear" a device for use in the human pedicles.

27. All calendars, log books, telephone logs, or other documents reflecting the daily activities and conduct of each deponent to whom this Notice of Deposition and the Subpoena Duces Tecum is addressed during the period from January 1, 1993 through the present.

28. All documents reflecting any FDA analysis of data with respect to spinal fixation devices which was generated pursuant to Investigational Device Exemptions granted to Acromed, Inc., Buckman & Company, Sofamor, S.N.C., Stuart, Smith & Nephew Richards, Inc., Zimmer, Advanced Spine Fixation System, Inc., and/or Cross Medical Products.

[Exhibits B and C omitted]

EXHIBIT D

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

[Caption omitted]

DECLARATION OF KATHLEEN L. WALKER

Pursuant to the provisions of 28 U.S.C. § 1746, I, Kathleen L. Walker, declare as follows:

1. I have been employed by the Food and Drug Administration ("FDA") since August 1983. I started with FDA as a nurse consultant in the Office of Device Evaluation ("ODE"), Center for Devices and Radiological Health ("CDRH"). I currently hold the position of Committee Management Officer in the Office of Management Services ("OMS"), CDRH. My responsibilities in this position are to provide administrative and program support to ODE in connection with the Medical Devices Advisory Committee, to prepare requests for personnel actions for Special Government Employees ("SGEs") in order to staff the committee, and to review the financial interests of SGEs to determine if there is a conflict of interest relating to a particular matter to be reviewed for a meeting or a special assignment.

2. FDA, which is a division of the Department of Health and Human Services, is responsible for ensuring the following: that foods are safe, wholesome, and sanitary; that human and veterinary drugs, biological products, and medical devices are safe and effective; that cosmetics are safe; and that electronic products that emit radiation are safe. Further, FDA is responsible for ensuring that regulated products are honestly and accurately represented to the consuming public and to health professionals.

3. CDRH is responsible for protecting the public health by helping to ensure that medical devices are safe and effective and that radiation exposure from electronic products is kept to a minimum. CDRH evaluates new medical devices for safety and effectiveness, and classifies new devices according to a regulatory scheme established under the Food, Drug, and Cosmetic Act ("the Act"). CDRH works with other divisions of FDA to initiate enforcement actions against products and manufacturers which are not in compliance with the Act.

4. ODE is principally responsible for evaluating the safety and effectiveness of medical devices before they are cleared for clinical research and marketing.

5. As a scientific regulatory agency, FDA and, in particular, CDRH, requires access to highly qualified expert advisors who can provide scientific and technical advice. Thus, FDA and CDRH use advisory committees (or advisory panels) to supplement the Agency's internal expertise and help the Agency staff stay current with "state-of-the-art" technology.

6. One such advisory committee is the Medical Device Advisory Committee, which is comprised of sixteen advisory panels (such as the Orthopedic and Rehabilitation Panel) . The panels review and evaluate data on the safety and effectiveness of marketed and investigational devices and make recommendations for their regulation. Each panel, according to its specialty area, performs the following tasks: to advise the Commissioner of FDA regarding recommended classification or reclassification of these devices into one of three regulatory categories; to advise on any possible risks to health associated with the use of devices; to advise on formulation of product development protocols; to review premarket approval applications for medical devices; to review FDA guidelines and guidance documents; to recommend exemption of certain devices from the application of portions of the Act; to advise on the necessity to ban a device; and to respond to requests for the FDA to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices. Each panel, according to its specialty area, may also make appropriate recommendations to the Commissioner of FDA on the quality in the design of clinical studies regarding the safety and effectiveness of marketed and investigational devices.

7. FDA's advisory committee members are appointed as SGES. An SGE is anyone who is retained, designated, appointed, or employed to perform temporary duties whether on a full-time or intermittent basis with or without compensation, for a period not to

exceed 130 days during any period of 365 consecutive days. This includes panel members, consultants, and experts.

8. All SGEs (who may serve as voting panel members, consultants, or experts to advisory committees) receive compensation for each day worked, including travel and per diem, unless such compensation and reimbursement is waived.

9. Finding qualified experts to continually staff the 148 member roster of the Medical Devices Advisory Committee is a difficult and time-consuming process. Relatively few individuals in this country possess the requisite background to serve on advisory panels, and can offer the kind of expertise which is needed to make the sophisticated judgments involved in medical device evaluation and classification. Moreover, many qualified experts choose not to participate on panels because the financial compensation is minimal and the inconveniences (time and travel) for participating on panels are often great.

10. Because advisory committees play such an important role in new product evaluation and classification, and because there is a limited pool of qualified experts who are able to serve on these panels, CDRH is very concerned about the implications of having panel members provide testimony in private litigation to which the federal government is not a party.

11. FDA and CDRH have several significant grounds for opposing the depositions of panel members. First, advisory panel members are provided access to confidential commercial information which relates to the products under evaluation and which the agency has a duty to protect. Second, CDRH is troubled by the prospect that qualified experts will simply choose not to serve on panels if they know that, as result of their service on the panels, they may be compelled to provide testimony in litigation to which they are not a party; indeed, in the past several panel members have expressed such concerns. This is especially true in cases such as this where all of the subpoenaed panel members are surgeons or professors who have extremely demanding schedules. Finally, many of the records

concerning the findings and recommendations of the panel are publicly available and, to the extent that they are publicly releasable, would be available to the litigants pursuant to a proper request.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Executed this 9th day of August, 1995.

/s/
KATHLEEN L. WALKER
Committee Management Officer
Office of Management Services
Center for Devices and Radiological Health
Food and Drug Administration

[Exhibits E and F omitted]

EXHIBIT G
IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

[Caption omitted]

DECLARATION OF LEELA RANGASWAMY, M.D.

Pursuant to the provisions of 28 U.S.C. § 1746, I, Leela Rangaswamy, declare as follows:

1. I am currently employed as an Orthopedic Surgeon at the Harvard Community Health Plan, in Boston, Massachusetts, and as a Staff Attending Orthopedic Surgeon at the Children's Hospital in Boston, Massachusetts. I serve as the Deputy Editor for the Journal of Bone and Joint Surgery. I am also a board examiner for the American Board of Orthopedic Surgery.

2. I received medical degrees from the Madras Medical College, Madras, India, and from the University of Delhi, Delhi,

India. I am licensed to practice medicine in New York, Delaware, and Massachusetts. I am board certified in orthopedic surgery.

3. I began a term as a Special Government Employee ("SGE") for the United States Food and Drug Administration ("FDA") on June 26, 1994. My term will end on August 31, 1998.

4. As an SGE, I am asked by FDA to perform temporary duties on an intermittent basis. I receive compensation for each day worked, including travel and per diem, unless such compensation and reimbursement is waived.

5. My employment as an SGE has been limited to serving as a panel member on the Orthopedic and Rehabilitation Devices Panel Meeting of July 21 and 22, 1994. This panel reviewed and evaluated data on the safety and effectiveness of marketed and investigational medical devices and made recommendations for their regulation.

6. I offered my services to act as an SGE because I believe that FDA advisory panels serve the public health through the review and evaluation of new medical devices. When I applied for the position, I did not anticipate that I would be required to provide deposition testimony in a private lawsuit regarding my work as a panel member.

7. My duties as a surgeon at two medical institutions and as an editor of a major medical journal demand a great deal of time and commitment. Although I believe that the work performed by the FDA advisory panels is a much needed public service, I would be hesitant to serve on future advisory panels if I knew that, as a consequence of such participation, I would be required to devote additional time providing testimony in private lawsuits.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Executed this 5th day of August, 1995.

/s/
Leela Rangaswamy, M.D.

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

[Caption omitted]

Transcript of Hearing Before Hon. Louis C. Bechtle, S.J.
August 17, 1995

* * * [154] * * *

THE COURT: The plaintiffs aren't worried. What they do, they do. What they presumably have to do in keeping with, I think, their reputation, they have had that many years, they may do the right thing. This may be of help, maybe not. It seems to me that a limited deposition — I say limited, possibly no more than a day, depending on what the answers are, it could be very short depending on the answers, it could be lengthy depending on the answers.

It seems to me that you have persons here who are, if you will, entangled with others. There is sufficient showing in the Court's view to have these depositions go forward.

Now, I worry a little bit, I wouldn't

[155] allow them to produce their patient calendars, because identification of patients is irrelevant. That thing would be obviously protected against the extent they need their own calendars, where they were, what they did, how they finished, and that would seem to be pertinent.

I don't see how that is difficult. Persons in high position have to understand occasionally within limits they will have to be, to some extent, inconvenienced.

Now, if doctors have a surgical schedule on a certain day or have to meet with the FDA, there's no question that those dates should be considered when arriving at these depositions.

I just don't think these persons are entitled to have — I have some doubt if there is a status of clothed agencies whose depositions are disfavored. I don't think these persons are in that status.

I think I tried to explain the reason why they are entitled to be deposed courteously, but I think firmly, fairly and fully in keeping with what has been requested here. * * *

[156] * * *

THE COURT: I don't think we, you and I, disagree from late '93 up to late '94 as kind of an industry, professional and government agency kind of affiliation that brought about a recommendation that this device be placed in a more favorable category from the vantage point of marketing.

Now, included in that affiliation were a number of persons. It hasn't been proven, but there is a sufficient showing here that substantial things of value passed to them or to the parties or persons that they worked for or their superiors of value from the industry.

[157] Now, without more, it seems to me, that just casts a shadow on the impartiality of their votes and their consultation on July 22 of 1994. Maybe there's nothing to it. I think the pointing of the questions the way they were suggested on these topics that have been mentioned, I think will bring it out promptly and presumably, if Dr. X or Y, including this five, this is my file in the Cohort, this is my file under oath, what I know, my viewpoint, I'm an advocate of this. I don't care about bias as it relates to the downgrading of the device from the vantage point of the professional standing of the individual. If a doctor has a belief in these devices, believes they should be downgraded, I don't have a problem with that. We have the suggestion, some persons close to it in higher position not on this list, were making decisions and at the same time receiving some benefit or some value or some advantage from those that will profit from this marketing. That, in my view, is sufficient need to allow the interest in protecting government's employees from testifying being relaxed to the extent that the plaintiffs seek to relax it, excluding inquiry concerning FDA acquired knowledge, FDA deliberations which the

[158] statute requires. * * * *

IN THE UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF PENNSYLVANIA

[Caption omitted]

Plaintiffs' Substituted Brief in Opposition
to AcroMed's Motion for Summary Judgment
or Partial Summary Judgment on the Grounds of
Preemption or Deference to Agency Expertise

Filed October 13, 1995

[Text of Brief omitted]

EXHIBIT 1
UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA
NEW ORLEANS

DOROTHY MARIE REEVES	:CIVIL ACTION :91-4689 "H"
VERSUS	:
ACROMED CORPORATION, ET AL.	:New Orleans, :Louisiana :Tuesday, August 30, 1993 :8:30 a.m.

Volume I of III

TRIAL BY JURY

BEFORE THE HONORABLE ADRIAN G. DUPLANTIER,
UNITED STATES DISTRICT JUDGE, presiding

* * *

[68] GEOFFREY J. PORTER, PLAINTIFF'S WITNESS,

SWORN CROSS-EXAMINATION * * *

Q. What is your position with AcroMed Corporation?
A. I'm vice-president and general counsel.
Q. You are also a stockholder in AcroMed Corporation, sir?
A. Yes, sir.
Q. Now, sir, what is AcroMed Corporation? What do you all do?
A. Manufacture and sell orthopaedic devices, specifically spinal implaints and instrumentation. * * *
[92] Q. Well, let me first ask you, sir, who is Mr. David Schlerf?
A. He works for the Buckman Company.
Q. Who is the Buckman Company?
A. The Buckman Company was the consultant of AcroMed at that time for FDA matters. * * *

[Testimony of Norman Welford]
[126] Q. Now, when did you first see this letter of January 10th, 1986?
A. Is that the letter from Schlerf?
Q. Yes, sir.
A. I have looked at the 510k which had been sent to me by Mr. Tschirn, and I noticed that this did not have many of the documents which one normally gets into a 510k when one is at FDA. One has the application from the manufacturer, and then one has comments and a sign-off sheet as it were with, maybe a few notes on it. So, I saw that there is a company in Washington which supplies copies under the Freedom of Information Act of 510k's. If they have them in stock, as it were, then you can get this very quickly. I called them and ordered this, actually, at the end of July, and they sent it down to me, and in that I found there was more information than I had previously from Mr. Tschirn.

[127] And in that were the notes of the reviewer who said "yes, this is the same thing as the VSP spinal plate." What I needed to clear up was what they intend to use this for.

So, in the normal course of events, what one does is, one just calls the company and says – in this case, the Buckman Company who was representing Acromed – and said to them "look, what is the intended use for this plate? I need a statement."

Q. So, why is it important for that reviewer to say "what is the intended use"?

A. Well, because as this had been declared what FDA calls NSE, or not substantially equivalent when it came in as the VSP spinal plate, then if this new application was for the same intended use as the previous one, it also would have been not substantially equivalent.

Q. So, if they stated that the 510k application with regard to December 20th and December 30th, 1985, was for spinal usage, then, in your opinion, would that have been approved or not?

A. In my opinion, it certainly would not have been approved.

Q. Just as the others had not been approved, is that correct?

A. Yes, correct.

Q. But, when, in response to that question about "what is

[128] the indications for use," when they say that the usage was specifically for arm or leg fractures or pelvis fractures, is that a different use than for the spine?

A. Exactly. It is a different use, and marketing permission is only for that use.

Q. So, does that appear when you have a product that is clearly for spinal application, yet Acromed tells the FDA that in their 510k application it is for long bone use, is that deceptive, in your opinion?

A. It would be deceptive if they did not intend to sell that just for long bone use.

Q. And if, in truth and in fact, they clearly intended to sell it, promote it, market it, distribute it for spinal implant, then, in your

opinion, would it be deceptive to tell the FDA that the indications of use are for fractured long bones?

A. If they did not truly intend those indications, of course it would be deceptive. * * *

[204] * * * EDWARD WAGNER, PLAINTIFF'S WITNESS, SWORN DIRECT EXAMINATION

Q. Mr. Wagner, were you ever employed by AcroMed Corporation, the defendants in this case?

A. Yes, I was.

Q. And what was your position with AcroMed Corporation, Sir?

A. President.

Q. And for how long were you president of AcroMed Corporation?

A. From 1983 until 1990. * * *

[206] * * * Q. Okay. Is it true, sir, that AcroMed Corporation was

[207] selling and/or distributing the VSP Spine Plate Fixation System before they even applied for 510K approval?

A. Yes. * * *

Q. I think you told us that as time went on, into the end of 1984 and the beginning of '85, you began selling to more and more doctors and hospitals, is that correct?

A. That's correct. * * *

[212] * * * Q. Now, is it true, sir, that the VSP Spine Plate Fixation System was for application to the spine, this system I'm holding in front of me was for application to the spine?

[213] A. That was its principal purpose. * * *

[229] * * * Q. Was this product marketed for spinal use?

A. Yes.

Q. Did Dr. Steffee make a video tape showing how it is used in the spine?

A. Yes, he did. * * *

[230] * * * Q. Did you know that he obtained a patent for this product for spine application?

A. Yes, yes.
Q. So, isn't the truth, sir, that this is a spine device, and indications for use are not for long bone, but, rather, for the spine? Isn't that the truth?
A. Principally, yes, yes. * * * *

[Testimony of Arthur D. Steffee]
[237] Q. Now, you applied for a patent for the VSP Spine Plate Fixation System, did you not, sir?
A. Through AcroMed, yes, sir. * * *
Q. And is there anything in that patent application that
[238] deals with this product, the VSP Spine Plate Fixation System being applied to an arm or a leg?
A. No, sir.
Q. The patent application is strictly with regard to a spine apparatus, is that correct?
A. That's correct.
Q. Which is what it is entitled on the first page, is that correct?
A. That's right.
Q. And, of course, as you go through the whole patent application, you describe the whole method of applying this to the spine, is that right, sir?
A. That's correct.
Q. Because that's what this product is, isn't it? It's a spine device?
A. It can be used for other reasons, but it is primarily for —
Q. That's not my question.
A. For the spine, yes.
Q. This product was patented by you as a spinal device, wasn't it?
* * *
[245] Q. You are familiar with the fact that in response to both of those applications in '84 and in '85, September of '85, the FDA clearly wrote and stated "Do not commercially distribute or market the product," aren't you?

A. That's what the document says.
Q. Yet, AcroMed continued to distribute and market the product, didn't they?
A. Yes, they did. * * * *

EXHIBIT 2

UNITED STATES PATENT
Steffee
Patent Number: 4,611,581
Date of Patent: Sep. 16, 1986

APPARATUS FOR STRAIGHTENING SPINAL COLUMNS
Inventor: Arthur D. Steffee, Moreland Hills, Ohio
Assignee: Acromed Corporation, Cleveland, Ohio

Appl. No.: 562,438
Filed: Dec. 16, 1983
Int. Cl. A61F 5/04
U.S. Cl. ..... 128/69; 128/92 B
Field of Search ..... 128/92 R

References Cited
U.S. PATENT DOCUMENTS

1,025,008	4/1912	Miner	128/92 D
1,789,060	1/1931	Weisenbach	128/92 A
3,244,170	4/1966	McElvenny	128/92 D
3,426,364	2/1969	Lumb	3/1.91
3,648,691	3/1972	Lumb et al.	128/92 D
3,659,595	5/1972	Haboush	128/93 D
3,693,616	9/1972	Roaf et al.	128/69
3,997,138	12/1976	Crock et al.	128/69
4,119,092	10/1978	Gil	128/92 D
4,185,624	1/1980	Gertzie	128/92 A
4,456,005	6/1984	Lichty	128/92 A

4,493,317 1/1985 Klaue ..... 128/92 D

FOREIGN PATENT DOCUMENTS

2806414 10/1978 Fed. Rep. of Germany

OTHER PUBLICATIONS

Zimmer, Warsaw, In. 1981 catalog p. B 186.
French Article "Rha natisme Veriebra" (Roy-Camille et al.)

Primary Examiner - Robert Peshock
Assistant Examiner - C.W. Shedd
Attorney, Agent, or Firm - Young & Tarolli

ABSTRACT

An improved apparatus is provided to reduce the extent of displacement between adjacent vertebrae in person's spinal column and to subsequently maintain the vertebrae in a reduced displacement relationship. When the apparatus is to be installed, holes are formed in the displaced vertebra and in vertebrae on opposite sides of the displaced vertebra. Force transmitting members are mounted in the holes in the vertebrae. A spinal plate is then positioned on the spinal column with the force transmitting members extending outwardly through slots in the spinal plate. Nuts are tightened on the force transmitting members connected with vertebrae on opposite sides of the displaced vertebra to anchor the spinal plate in place. A nut on the force transmitting member connected with the displaced vertebra is then tightened to pull the displaced vertebra to a desired position. In one embodiment of the invention, the force transmitting member has a relatively large diameter helix which engages a side wall of the hole in the displaced vertebra. In another embodiment of the invention, an insert is positioned in a hole in the displaced vertebra and expanded by the force transmitting member to securely grip the vertebra.

8 Claims, 14 Drawing Figures * * * *

[Exhibits 3-4 omitted]

EXHIBIT 5

Buckman Company, Inc.
921 Calle Verde
Martinez, California 94533
(415) 372-7740

September 20, 1985

Food and Drug Administration
Office For Device Evaluations
Document Control Center (HFZ-401)
8757 Georgia Avenue
Silver Spring, MD 20910

Variable Screw Placement (VSP)
Spine Plate Fixation System
Number K843600

Dear FDA,

Not withstanding the fact that the Center for Devices and Radiological Health neglected to comply with the 90-day review period set forth in section 510(k) of the Federal Food, Drug and Cosmetic Act, the enclosed clinical data is submitted in response to the Center's letter (copy enclosed) of December 19, 1984, pertaining to your request for additional information in support of our 501K Notification filed on September 12, 1984.

The data specifically addresses your comments regarding a larger sample population, multiple investigators and longer follow up. AcroMed, in its original submission coupled with this supplemental response, has provided information in excess of that required by applicable regulations to meet the criteria necessary to establish substantial equivalency.

The information presented in this submission places K843600 in condition so that the Center is compelled to grant a finding of substantial equivalence. AcroMed respectfully requests that it be notified expeditiously of such a finding. For any further questions, please do not hesitate to contact me.

Sincerely,

/s/
Pamela M. Buckman R.N., M.S.

cc: Ed Wagner, AcroMed
Joe Radzius

PMB/ps
Enclosure: VSP Clinical Report (3 copies)

[Exhibit 6 omitted]

EXHIBIT 7

Buckman Company, Inc.
921 Calle Verde
Martinez, California 94533
(415) 372-7740

December 20, 1985

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
8757 Georgia Avenue
Silver Spring, MD 20910

Re: 510K Notification

Dear Document Control Clerk:

The attached information is submitted in accordance with Part 807, Subpart E of the code of Federal Regulations Chapter I, Title 21.

It is our opinion that the AcroMed Nested Bone Plate is substantially equivalent to devices manufactured and marketed prior to May 29, 1976. We conclude that the following information supports our position.

AcroMed Corporation considers certain information in this document to be of a confidential proprietary nature. Specifically, the engineering drawings and the section headed "description of the device" should not be released through freedom of information act requests or any other way. AcroMed Corporation agrees to notify FDA when there is a change in this status.

As the official correspondent for AcroMed Corporation for this product line, please direct any correspondence relative to it to my attention at the address indicated for Buckman Company, Inc.

We thank you in advance for your prompt consideration of this submission and will be happy to provide additional information as you may require.

Sincerely,

/s/
David W. Schlerf

DWS/db
cc: Ed Wagner, AcroMed Corporation
Enclosure: 510K Notification (3 copies)

510K PREMARKET NOTIFICATION
AcroMed Nested Bone Plate

NAME OF THE DEVICE:

Trade Name: AcroMed Nested Bone Plate

Common Name: Bone Plates

ESTABLISHMENT REGISTRATION NUMBER:

Number 1526439

CLASSIFICATION:

Bone plates have been classified as Class II medical devices. Performance Standards are applicable.

PERFORMANCE STANDARDS:

To our knowledge, no Performance Standards have been promulgated for bone plates. Until such time as appropriate Performance Standards are developed and published, the manufacturer intends to produce the device according to the regulations and standards that are appropriate to the risk that Class II devices reasonably represent.

LABELING:

Each device will be serial numbered and individually packaged with the following draft label affixed to the package. The labeling will also contain the appropriate cautionary note against intermixing plates and screws of different alloy types.

Proposed Label Sample

AcroMed Nested Bone Plate
316 L stainless steel *

Serial No.: xxxxxx
Contents: One (1)
Size: 160 mm (4 hole)

CAUTION: For sale to or on the order of a physician.

For use in conjunction with plates and screws made of the same alloy

DO NOT MIX DIFFERENT METALS

CLEAN ONLY NOT STERILE

Manufactured For
AcroMed Corporation
2450 Prospect Avenue
Cleveland, OH 44115

* The labeling for the titanium alloy plates will be the same except that this line will indicate "6AL, 4V, TI titanium alloy".

DESCRIPTION OF THE DEVICE:

The AcroMed Nested Bone Plates will be manufactured from 316 L stainless steel surgical implant alloy. This material has been utilized for many years. Additionally, plates made from 6AL, 4V, TI surgical implant titanium alloy are planned. The titanium plates will be introduced according to medical demand and evolving surgical judgement. The physical configuration

and dimensions of the plates will be identical for both alloy types.

The plates will be produced and machined in such fashion that the holes are elongated into "slots" similar to those of the older style "Eggers" plate or the oval elongated slots typical of compression type bone plates. Additionally, each slot has been machined to produce a series of adjacent shallow notches (nests) on the upper slot surface only to allow the appropriate bone screws to seat firmly and securely at the selected location within each slot.

A variety of sizes will be available and defined by descriptors such as 100 mm, 140mm, 160mm or 2, 3, 4 holes, etc. Plates with an additional terminal slot, one half the standard length, will also be available. These plates will be identified by appropriate length in mm and as being 2 1/2 hole, 3 1/2 hole etc. Nominal thickness of both plate alloy types is 4.8 mm.

Serial numbers and sizes as well as the AcroMed Logo will be etched into the finished lateral surface of each plate. This will help positively identify each plate intraoperatively or at such time as the plates might be separated from their packaging materials.

All plate surfaces will be passivated and electropolished. All corners and intersecting surface angles will be radiused. The plates will be stress relieved by an accepted controlled heat, slow cool process. The manufacture of the titanium plates will be likewise except that they will exhibit a "dull" anodized matte finish.

Any required bending, shaping or other modification of the plates necessary to accommodate individual anatomic variations will be accomplished with the use of already approved available orthopaedic instrumentation, bending irons and templates.

Representative graphic examples of the AcroMed Nested Bone Plate are included as engineering drawings in Exhibit I.

INSTRUMENTATION:

No special instrumentation is required. The AcroMed Nested Bone Plate has been designed to utilize existing general orthopaedic instrumentation for their insertion and/or modification.

SUBSTANTIAL EQUIVALENCE:

Other than the "multiple nesting" of the slots, there is no new application, indication, material, device configuration or specification presented here. The AcroMed Nested Bone Plate is substantially equivalent to many current and preammendment devices intended for use in orthopaedic fixation and stabilization of osseous fractures.

Such preammendment and substantially equivalent devices include, but are not limited to: The Modified Eggers bone plate, A O (DCP) bone plates, Synthes bone plates, ASIF bone plates, Smith Kline Surgical Specialties bone plates and bone plates manufactured by King Manufacturing, DePuy, Richards Medical Company and Zimmer USA as well as many lesser known companys. The use of titanium as a preammendment implant alloy is established by the Zimmer USA/Coonrad total elbow and the Thompson Corporation titanium wrist fusion implant. The Ace Medical Company marketed a similar "slotted" titanium bone plate with a single "nest" in the center of each slot several years ago. The Ace device was approved via the 510K process. Exhibit II contains preammendment device references.

[Exhibits to 510(k) Premarket Notification omitted]

EXHIBIT 8

Buckman Company, Inc.
921 Calle Verde
Martinez, California 94533
(415) 372-7740

December 30, 1985

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
8757 Georgia Avenue
Silver Spring, MD 20910

Re: 510K Notification

Dear Document Control Clerk:

The attached information is submitted in accordance with Part 807, Subpart E of the code of Federal Regulations Chapter I, Title 21.

It is our opinion that the AcroMed Cancellous Bone Screw is substantially equivalent to devices manufactured and marketed prior to May 28, 1976. We conclude that the following information supports our position.

AcroMed Corporation considers certain information in this document to be of a confidential proprietary nature. Specifically, the engineering drawings and the section headed "description of the device" should not be released through freedom of information act requests or any other way. AcroMed Corporation agrees to notify FDA when there is a change in this status.

As the official correspondent for AcroMed Corporation for this product line, please direct any correspondence relative to it to my attention at the address indicated for Buckman Company, Inc.

We thank you in advance for your prompt consideration of this submission and will be happy to provide additional information as you may require.

Sincerely,

/s/
David W. Schlerf

DWS/db
cc: Ed Wagner, AcroMed Corporation
Enclosure: 510K Notification (3 copies)

510K PREMARKET NOTIFICATION
AcroMed Cancellous Bone Screw

NAME OF THE DEVICE:

Trade Name: AcroMed Cancellous Bone Screw
Common Name: Bone screws

ESTABLISHMENT REGISTRATION NUMBER:

Number 1526439

CLASSIFICATION:

Bone screws have been classified as Class II medical devices. Performance Standards are applicable.

PERFORMANCE STANDARDS:

To our knowledge, no Performance Standards have been promulgated for bone screws. Until such time as appropriate performance standards are developed and published, the manufacturer intends to produce the device in accordance with the regulations and standards that are appropriate to the risk that Class II devices reasonably represent.

LABELING:

Each device will be individually packaged and lot numbered with the following draft label affixed to the package. AcroMed also intends to produce, package and sell the screws in multi packs such as 2, 3, 4, etc. of the same or assorted size screws per package. Inasmuch as AcroMed intends to produce both stainless steel and titanium screws, an appropriate warning against intermixing screws and plates of dissimilar metals will be included.

Proposed Label Sample

AcroMed Cancellous Bone Screws
316 L stainless steel *

Serial No.: xxxxxx
Contents: One (1)
Size: Length 160 mm
Diameter 6.62 mm

CAUTION: For sale to or on the order of a physician.

For use in conjunction with plates and screws made of the same alloy

DO NOT MIX DIFFERENT METALS

CLEAN ONLY NOT STERILE

Manufactured For
AcroMed Corporation
2450 Prospect Avenue
Cleveland, OH 44115

* The labeling for the titanium alloy screws will be the same except that this line will indicate "6AL, 4V, TI titanium alloy".

DESCRIPTION OF THE DEVICE:

The AcroMed Cancellous Bone Screws will be manufactured from 316 L stainless steel surgical implant alloy. Additionally, screws made from 6AL, 4V, TI surgical implant titanium alloy are planned. The titanium screws will be introduced according to medical demand and evolving surgical judgement.

The screws will be produced and machined in such fashion that they will exhibit the general physical configuration of a "Hagie-type" pin, including the removable hex nuts. The shaft of each pin has been manufactured with a hex drive and section to facilitate insertion. A variety of sizes will be available, such as, 30 mm through 160 mm in 2-4 mm increments. Initially, three different pin diameters will be offered for each available length. At present, screws with major cancellous diameters of 5.5mm, 6.5mm and 7.0mm are planned. Major machine screw diameter of the pin shaft will be 4.75 mm and of 10/32 pitch. Additional sizes will be added based on medical demand.

The 3/8" hex nuts are drilled and tapped to accommodate the 10/32 machine thread on the 4.75 mm shaft of the screws. Hex nuts of different sizes will be added to accommodate the above changes in pin shaft diameter at the appropriate times.

Each screw will have either an "S" or "T"etched into the finished hex drive surface of each screw shaft. Each hex nut will be likewise identified. This will help to positively identify the screw/nut alloy types intraoperatively or at such time as the screws might be separated from their packaging materials.

All screw and hex nut surfaces will be smooth and polished. All corners and intersecting angles will be radiused. The manufacture of the titanium screws and nuts will be the same.

Representative deminsions and configuration of the AcroMed Cancellous Bone Screws are included as engineering drawings in Exhibit I.

INSTRUMENTATION:

Instrumentation is required to insert and anchor the AcroMed Cancellous Bone Screws and hex nuts. The screws/nuts have been designed to utilize general orthopaedic instrumentation of the appropriate size and configuration.

SUBSTANTIAL EQUIVALENCE:

There is no new application, indication, material, device configuration or specification presented here. The AcroMed Bone Screw is substantially equivalent to many current and preammendment devices intended for use in orthopaedic fixation and stabilization of osseous fractures where metalic screws or plates and screws are indicated.

Such preammendment and substantially equivalent devices include, but are not limited to: The A O System of cancellous bone screws and cancellous bone screws such as those produced by King Manufacturing, DePuy and Zimmer USA as well as many lessen known companys. DePuy and Zimmer USA also produced the previously mentioned preammendment "Hagie-type" pins.

The use of titanium as a preammendment implant alloy is clearly established by the Zimmer USA/Coonrad total elbow and the Sampson Corporations titanium wrist fusion implant. Ace Medical Company also marketed and sold a titanium bone screw and plate that was approved via the 510K process. Examples of substantially equivalent devices are included in Exhibit II).

[Exhibits to 510(k) Premarket Notification omitted]

EXHIBIT 9

Buckman Company, Inc.
921 Calle Verde
Martinez, California 94533
(415) 372-7740

January 10, 1986

Kenneth McDermott
Food and Drug Administration

Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
8757 Georgia Avenue
Silver Spring, MD 20910

Re: K#855224
AcroMed Nested Bone Plate

Dear Kenneth:

Thank you for your prompt attention to this matter. This letter is sent in response to your telephone request for additional information. If I understood you correctly, the only area of concern you addressed was the need for a more definitive statement covering the intended "indications for use" of the AcroMed Nested Bone Plate.

The proposed indications for use for the AcroMed device are the same general indications proposed for the AO system of plates. More specifically, (for the purpose of this 510K), the AcroMed plates are intended for use in appropriate fractures of long bones of both the upper and lower extremity and such other flat bones (as in the fractured pelvis) that may from time to time require stabilization with contourable metallic non-compressing plates.

Kenneth, I hope that the above statements provide you with the information necessary to allow for the timely approval of this submission. In the event that you still require additional information, please do not hesitate to call me at (415) 372-7740.

In closing, allow me to again thank you for your courtesy and promptness in reviewing this 510K Notifcation.

Sincerely,

/s/
David W. Schlerf

SWD/cb
cc: Edward Wagner, President, AcroMed Corporation

EXHIBIT 10

[Feb 18 RECD]

Department of Health & Human Services
Public Health Service
Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

Re: K860017 AcroMed Cancellous Bone Screw

Mr. David W. Schlerf
Buckman Company, Inc.
921 Calle Verde
Martinez, California 94553

Dated: December 30 and 31, 1985
Received: January 3, 1986

Dear Mr. Schlerf:

We have reviewed your Section 510(k) notification of intent to market the above device and we have determined the device to be substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market your device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) until such time as your device has been classified under Section 513. At that time, if your device is classified into either class II (Performance Standards) or class III (Premarket Approval), it would be subject to additional controls. Please note: This action does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or regulations.

General controls presently include regulations on annual registration, listing of devices, good manufacturing practice, labeling, and the

misbranding and adulteration provisions of the Act. In the future, the scope of general controls may be broadened to include additional regulations.

All regulations and information on meetings of the device advisory committees, their recommendations, and the final decisions of the Food and Drug Administration (FDA) will be published in the Federal Register. We suggest you subscribe to this publication so you can convey your views to FDA if you desire and be notified of any additional requirements imposed on your device. Subscriptions may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. Such information also may be reviewed in the Dockets Management Branch (HFA-305), Food and Drug Administration, Room 4-62, 5600 Fishers Lane, Rockville, Maryland 20857.

This letter does not in any way denote official FDA approval of your device or its labeling. Any representation that creates an impression of official approval of this device because of compliance with the premarket notification regulations is misleading and constitutes misbranding. If you desire advice on the labeling for your device or other information on your responsibilities under the Act, please contact the Office of Compliance, Division of Compliance Operations (HFZ-320), 8757 Georgia Avenue, Silver Spring, Maryland 20910.

Sincerely yours,
/s/
Kshitij Mohan, Ph.D.
Director
Office of Device Evaluation
Center for Devices and Radiological Health

[Feb 18 RECD]

Department of Health & Human Services
Public Health Service
Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

Re: K855224
AcroMed Nested Bone Plate

Mr. David W. Schlerf
Buckman Company, Inc.
921 Calle Verde
Martinez, California 94553

Dated: January 10, 1986
Received: January 17, 1986

Dear Mr. Schlerf:

We have reviewed your Section 510(k) notification of intent to market the above device and we have determined the device to be substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market your device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) until such time as your device has been classified under Section 513. At that time, if your device is classified into either class II (Performance Standards) or class III (Premarket Approval), it would be subject to additional controls. Please note: This action does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or regulations.

General controls presently include regulations on annual registration, listing of devices, good manufacturing practice, labeling, and the misbranding and adulteration provisions of the Act. In the future,

the scope of general controls may be broadened to include additional regulations.

All regulations and information on meetings of the device advisory committees, their recommendations, and the final decisions of the Food and Drug Administration (FDA) will be published in the Federal Register. We suggest you subscribe to this publication so you can convey your views to FDA if you desire and be notified of any additional requirements imposed on your device. Subscriptions may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. Such information also may be reviewed in the Dockets Management Branch (HFA-305), Food and Drug Administration, Room 4-62, 5600 Fishers Lane, Rockville, Maryland 20857.

This letter does not in any way denote official FDA approval of your device or its labeling. Any representation that creates an impression of official approval of this device because of compliance with the premarket notification regulations is misleading and constitutes misbranding. If you desire advice on the labeling for your device or other information on your responsibilities under the Act, please contact the Office of Compliance, Division of Compliance Operations (HFZ-320), 8757 Georgia Avenue, Silver Spring, Maryland 20910.

Sincerely yours,

/s/
Kshitij Mohan, Ph.D.
Director
Office of Device Evaluation
Center for Devices and Radiological Health

EXHIBIT 11
INVESTIGATIONAL DEVICE EXEMPTION
VARIABLE SCREW PLACEMENT (VSP) SYSTEM
FOR
SPINAL APPLICATIONS

Sponsored by
ACROMED CORPORATION
CLEVELAND, OHIO

Submitted by Buckman Company, Inc.
January 17, 1986

*** PURPOSE OF THE STUDY: The purpose of the study is to provide evidence that supports the use of the VSP Spine Plate System to achieve stability in the adult spine. Surgical use of the system is primarily intended to achieve the following clinical results:

1. Reduction in pain.
2. Increase in function

RATIONALE: In the past attempts at stabilizing back surgery have involved two stage procedures: a posterior procedure followed by an anterior operation approximately two weeks later. The double jeopardy type of surgery requires two excursions under anesthesia, and a longer, more difficult recovery. The fact that spine plate surgery is a one-stage, posterior approach eliminates these obvious disadvantages. A second consideration is that in the past most efforts to stabilize an unstable spine involved a distraction method of correction. This straightens the spine, giving the patient a forward tilt, ie., loss of lordosis, which in turn disrupts balance, gait and posture.

The newly designed spine plates, by comparison, can be easily bent in surgery to conform to, or create, the patient's lordotic curve.

Maintenance of either a lordosis or thoracic curve is essential to good mobility and balance following surgery.

Another advantage to spine plating was the immediate, solid fixation could be achieved. No other form of bracing, casting or any other type of immobilization would be required. The patient could then be expected to ambulate more quickly both with and without assistance. Furthermore, the elimination of immobilization would prevent the hazards associated with stress deprivation, which hinders the patient's recovery. The hospital stay could thereby be reduced when compared to other comparable types of back surgery.

NOTE: Rationale section above provided by Arthur Steffee, M.D., Primary Investigator for the Study

INDICATIONS FOR USE: The VSP Spine Plate System will be studied in patients with any condition of the spine resulting in instability. The specific diagnoses may include the following:

1. Degenerative, true and traumatic spondylolistheses
2. Traumatic or pathological fractures
3. Failed back syndrome
4. Pseudoarthrosis
5. Instrumentation failure
6. Tumors
7. Adult degenerative and paralytic scoliosis
8. Degenerative disc disease

SAMPLES AND POPULATION: The study subjects will number 200 to 250 adult patients. Subjects will be entered from multiple test sites. A minimum of three institutions from three different geographical locations has been established. The study will be expanded to other locations as Orthopaedic Surgeons agree to the protocol and obtain Institutional Review Board approval. * * * *

EXHIBIT 12

AcroMed Corporation
2450 Prospect Avenue
Cleveland, Ohio 44115
216/771-5800

January 16, 1986

Michael R. Zindrick, M.D.
Hinsdale Orethopedic Associates, S.C.
550 North Monroe Street
Hinsdale, IL 605221

Dear Dr. Zindrick:

Belated though it is, my thanks for sending a copy of the AO manual on spinal plate fixation. Unfortunately, the manual's second edition is dated 1979, which is three years too late to establish a pre May, 1976 use for a reference for our plates and screws. I was able to locate a copy of the first edition (1969), but there was no appropriate reference. Without an applicable citation, we have prepared and today sent an IDE for the VSP Spine Plates and Screws to FDA.

In the meantime and until the IDE is completed, we have acceded to FDA's position that we refer to the plates as "bone plates" and the screws as "bone screws," a labeling slight-of-hand that satisfies the agency's regulations but in no way changes the intended use of the plates and screws. As one of the FDA staffers commented, bones are bones, and it is the judgment of the surgeon that controls the use of the implants.

See you in New Orleans.

Sincerely yours,

/s/

Edward J. Wagner
President

EJW:sh

[Exhibit 13 omitted]

EXHIBIT 14
MEMORANDUM OF INTERVIEW
WITH ROBERT A. TAYLOR

Robert A. Taylor
7560 Hollycroft Apt. E5
Mentor, Ohio
(216) 255-4437

At about 6:30 pm, accompanied by R. M. Koeninger, I visited Mr. Taylor and interviewed him regarding his knowledge of events which occurred while he was employed by Acromed Corp., 3303 Carnegie Ave., Cleveland, Ohio.

Mr. Taylor came to work at Acromed in the fall of 1984. He was to implement a quality control and GMP program and become V.P. of Operations. As V.P. of Operations, he had little to do with sales of products made/sold by or for Acromed. His was primarily the acquisition, design and quality aspects of the operation. He said that Ed Wagner initially put together the Catalog.

He knew that in late 1985 that a lawyer, (later identified as Joe Radzius), Ed Wagner, Dr. Steffee and possibly Pam Buckman went to visit Medical Devices personnel to see if there was not some way to put the devices into the market. He overheard discussions in which the participants and to meetings with CDRH had said they were told how to put their devices in the market, i.e. as bone plates. Then to study the devices for use in the spine as spine plates and

pedicle screws. They were for spine use. He said they spent a lot of money on research with the various doctors to get the plates and screws approved for spine use. He said promotion was done by word of mouth, at conventions and by referring doctors who were not on the list of approved customers to Dr. Steffee for training. They would not sell to anyone not trained by Steffee or by a Steffee associate because Acromed and Steffee did not want VSP plates to be improperly used.

As part of his job, Taylor would take the calls referred to him by customer service if they had a problem customer. He cited one example of a Cleveland area doctor who demanded that the plates and screws be sent to him immediately because he intended to do plate implantation the following day. The policy of refusing to ship to an unapproved customer was upheld by customer service and when the doctor became furious and abusive he was referred to Taylor who said he steadfastly held to Acromed's policy of not shipping VSP systems to unapproved customers. Koeninger asked him, "What if the doctor had represented that he wanted to use the device in an arm or leg, would you (Acromed) have shipped them?" Mr. Taylor responded that he would not have approved the shipment even for that use unless the doctor had "scrubbed" with Dr. Steffee and was approved.

Harriet Foster was the senior customer service person who received orders and made initial checks into customer "approved status".

Taylor said he had heard that one or two VSP plates had been tried on long bones, but he was not sure it was true.

Taylor was not aware of how many sets of plates and screws had been sold, but said there were "thousands and thousands of sets of plates shipped."

Taylor was asked about the clamps and if they were approved. He said they were not, but were dropped primarily because they were

not as effective as had been hoped. He said they had shipped the plastic pedicle spacer to doctors and had tried to market the device as a "Custom" device, but stopped after notice from FDA. He said the device was one which had to be on hand before surgery began because the need for it was never certain until the surgeon got into the back.

We asked Taylor how he handled complaints about screws that failed or "broken screws". His response was that even though the screw broke, the patient might have had a complete fusion and the back would be repaired. This was not considered a failure of the device. He said they rarely ever received notice from hospitals or surgeons that the screws had failed or broke at Acromed's Corporate offices. He said these reports usually were made first hand by the surgeon at the display booths at the conventions. This reporting was handled by referring the physician to Dr. Steffee who usually attended the conferences and manned the booths part of the time. They would simply tell the doctor, "Dr. Steffee will be here about 2:00 pm, please come back then and he will be able to help you, that is not our area of expertise".

Taylor said he sat in on many "idea" meetings where doctors, "who are all inventors", proposed ideas and the design folks would evaluate it. Some, maybe a few percent, were thought to be worthy of any serious follow-up after only cursory review of engineers. Some had been developed.

Taylor said persons (doctors) fully interested in use of VSP system were referred to Steffee for training. He said that Steffee had done training at several locations in the United States when sufficient candidates were present. Steffee might also scrub with the doctor if he was in the area for some other purpose.

Taylor said Acromed had originally had a small clientele of approved customers who would be able to schedule surgeries early

enough to order the needed devices from Cleveland and not maintain large inventories. He said that Dr. Brown, Human Hospital in Miami had a practice where he did numerous trauma repairs and that his brother, Tony Brown, had become the first Acromed dealer. He maintained a stock of devices for emergency use and later provided devices to other surgeons. Taylor thought the approved doctor list was maintained by the dealers also. Since the first dealer, several had been established.

The new president of Acromed is the owner of the Dutch subsidiary of Acromed, Ortomed. Taylor had gone to Holland to oversee GMP setup and advise on the production requirements for the VSP system there. Acromed purchased the stainless steel and shipped it to Ortomed for use in producing VSP. All the VSP system components made by Ortomed are sold in Europe. None are imported into U.S.A.

Subsequent to our initial discussion of these facts, Farr revisisted the issue of controlling the sales to exclude all except those who knew how to use it in the spine. Taylor said the device was always intended for use in the spine and was never distributed to parties who were not known to have the skills and training to implant in the spine. Complaints were voiced at the booth at conventions by doctors, but rarely reported to the firm directly. Farr asked against about how the product was promoted and was told, generally referrals, word of mouth, medical article generated journal entry inquiries and then referral to Steffee for training.

Taylor encountered Buckman and Associates as part of their studies. He said a lot of money was being spent on the studies. Taylor said Buckman is no longer doing the studies, only consulting and using the study data base developed by Buckman on VSP.

We thanked Mr. Taylor for the cooperation and told him that he would likely be visited again in the future as the investigation progresses.

/s/
Leonard J. Farr

[Exhibits 15-18 omitted]

EXHIBIT 19

* * *

DEPARTMENT OF HEALTH & HUMAN SERVICES

[Handwritten: 12/22/89 [illegible] 00204 [illegible] Greensboro RP Please visit 2 NC Hospitals within the next 2 weeks and get info requested by CinDO]

Date: December 18, 1989

From: L.J. Farr Compliance Officer
Clinical District

Subject: Investigation Request — Arthur Steffee, MD
Acromed Inc.
Cleveland, Ohio

To: Director of Investigations
Branch, Atlanta District

Variable Screw Placement (VSP)
Bone Plates and Screws

Hospitals: Durham County
General Hospital
Durham, N.C.

Duke University
Durham, N.C.

Following an ad hoc meeting with CDRH, OE and GCF-1, CinDO is developing evidence to support an injunction and needs assistance in the form of a prompt and detailed investigation as is requested below. Facts in hand show that Arthur Steffee, MD, an orthopedic surgeon, has developed several spinal implant devices for use in stabilizing the spine for various injuries and with fusion surgeries. These are marketed though Acromed, Inc. In 1985, the AcroMed, Inc. firm, through its monitor firm – the Buckman Company of Martinez, Calif. submitted a 510K for The Variable Screw Placement (VSP) Spinal Fixation System which included stainless steel slotted plates, washers and screws for the purpose of implanting with intended use in spinal fixation. The firm was told this was not a Class II device as it was not substantially equivalent to any existing device or pre-amendment device and that 501K would not suffice, but that on IDE and subsequent PMA would be required for marketing the device system for spinal fixation surgery.

The firm subsequently met with CDRH's Office of Device Evaluation. This meeting resulted in the firm recognizing that the parts of its system could be 510K approved as equivalent (substantially) to other devices and that FDA could not prohibit surgeons from using the devices as they chose. The firm submitted 510Ks for parts of the devices, plates screws, washers separately. The declared use of the plates in the 510K was for long bones of the upper and lower extremities and flat bones such as the pelvis. The firm was warned against promoting the devices for use in spinal surgery.

Subsequently the firm set about submitting an IDE and called its devices in the IDE "Variable Screw Placement Spinal Fixation Plates (VSP) and Transpedicular Screws". Several physicians have conducted studies on this sytem. However, the firm has marketed many thousands of the VSP plates and screws to hospitals and surgeons for use in spinal fixation surgery without sanction of the

Investigational Device Exemption by providing the intended use through seminars, training, publication, and word of mouth recommendations by surgeons who were involved in the IDE work.

* * * *

[Exhibits 20-22 omitted]

EXHIBIT 23

Department of Health and Human Services
Public Health Service
Food and Drug Administration

District Address and Phone Number:
1141 Central Parkway
Cincinnati, OH 45202
(513) 684-3501

Date of Inspection: 7/14, 17-20, 25-27 & 8/17/89

Type Establishment Inspected: IDE Study Sponsor

Firm Name: AcroMed Corporation

Name of Firm, Branch or Unit Inspected: same

Street Address: 3303 Carnegie Avenue

Street Address of Premises Inspected: same

City and State: Cleveland, OH 4415

City and State: same

During an inspection of your firm, (I) (we) observed:

IDE G860013 involved the use of VSP Spine Plates, VSP Transpedicular Screws and VSP Plate Clamps for spine stabilization. The

plates and screws were the same as plates and screws being marketed as VSP Bone Plates and VSP Bone Screws.

* * *

5. COMMERCIALIZATION
   a. During the time of the IDE studies and after they ended, bone plates and bone screws were sold to hospitals for spinal use by non IDE physicians. IDE Spine Plates were sold to St. Vincent Charity Hosp. after Dr. Steffee's last subject. Doctors (IDE and nonIDE) were trained how to perform the operation by Dr. Steffee (Chairman of the Board of AcroMed). Data for these nonIDE patients have been collected on the same patient information forms used during the IDE study.
   b. VSP Plate Clamps [handwritten: buttress clamps] were sold to non IDE hospitals during the IDE study and to Non IDE and IDE hospitals after the study.
   c. AcroMed has distributed video tapes and VSP Plating System Technique Manuals showing spinal use of these plates and screws. [Handwritten: ?promotion]

Employee(s) Signature: /s/
Employee(s) name and title: Frederick M. Lochner, Investigator

EXHIBIT 24

Department of Health and Human Services
Public Health Service
Food and Drug Administration

District Address and Phone Number:
1141 Central Parkway
Cincinnati, OH 45202
(513) 684-3501

Name of individual to whom report issued: Dr. Arthur D. Steffee

Date of inspection: 6/22, 23, 26-28, 7/6, 13, 21, 8/22, 29/89

Type of individual: M.D.

Type establishment inspected: Clinical Investigator

Firm name: Arthur D. Steffee, Inc.

Name of firm, branch or unit inspected: same

Street address: 2709 Franklin Blvd.

Street address of premises inspected: same

City and state: Cleveland, OH 44113

City and state: same

During an inspection of your firm, (I) observed:

IDE G860013 involved the use of VSP Spine Plates, VSP Transpedicular Screws and VSP Plate Clamps for spine stabilization. The plates and screws were the same as plates and screws being marketed as VSP Bone Plates and VSP Bone Screws.

* * *

4. Dr. Steffee trained both IDE and non IDE doctors how to use the plates, screws, and clamps for spine stabilization. He and/or people in his office prepared materials (video tapes, booklet, technique manual) showing the use of these devices for spinal use.

Employee(s) signature: /s/
Employee(s) name and title: Frederick M. Lochner, Investigator

EXHIBIT 25

CONFIDENTIAL
SUBJECTIVE TO PROTECTIVE ORDER

III. SITUATION ANALYSIS

The following narrative of the current market situation provides an assessment of competition and competitive activities, market trends, changes in technology, the regulatory environment, our products, our customer service, physical distribution and service levels, our distributors, and our customers' attitudes toward the company.

VSP System

The overriding marketing consideration for VSP Plates and Screws in FY 90 has been the regulatory environment. The FDA has increasingly brought pressure on AcroMed (as well as its competitors), AcroMed's customers and its distributors to insure that these products were not being promoted for non-indicated uses.

As a result, we have had to be extremely circumspect in our approach to surgeons. We continue to maintain a posture of marketing Bone Plates and Bone Screws, while continuing our responsibility of providing information and educational avenues for surgeons who choose to use these products for spinal fixation.

We have used a variety of educational vehicles to this end. The most productive of these have been Institutional-sponsored seminars on pedicle fixation, regional and national professional meeting which include a laboratory or workshop on pedicle fixation, and a visiting surgeon program with the Cleveland Spine and Arthritis Center of two to three days to observe implantation techniques of these devices. We have maintained a low profile by not sponsoring or officially participating in these forums except as exhibitors where appropriate.

We have also continued to enforce our policy of not selling to any surgeon who has not attended a VSP seminar, scrubbed in with an experienced VSP user, or who does not have significant experience with pedicle fixation using other systems. * * * *

[Exhibits 26-27 omitted]

EXHIBIT 28

AcroMed Corporation
2450 Prospect Avenue
Cleveland, Ohio 44115
216/771-5800

CONFIDENTIAL
SUBJECT TO PROTECTIVE ORDER

April 18, 1986

Tony Brown
R.A. Brown & Associates
7800 Red Road
Suite 304
Miami, FL 33134

Dear Tony:

With reference to our telephone conversation on April 14 about your participation in assisting us in developing a comprehensive marketing program for our existing and projected products, I want to take this opportunity to outline our thoughts as they exist at this time about the scope and direction of the program. The information furnished to you is regarded by us as confidential and proprietary and therefore is not to be shared in whole or in part with any other person.

By way of background . . . we are selling our VSP Bone Plates and VSP Bone Screws without a formal marketing program, indeed without any marketing or sales staff and without any advertising. Dr. Steffee has "promoted" the device with other surgeons through word-of-mouth, technical exhibits, published papers, educational conferences and the like. This approach has been assisted and reinforced by informal endorsements by other surgeons. In two years plus it has proven to be reasonably effective. Pending completion of the IDE/PMA and FDA's approval, we cannot yet

state explicitly that the plates and screws are for use specifically in the spine: In the meantime we are restricted to calling them "Bone" Plates and Screws, though they can be used in thge spine. I expect we will complete the PMA in about 36-40 months. * * * *

[Exhibits 29-47 omitted]

EXHIBIT 48

DATE: 9/11/91

TO: Donald F. Fernholz
SCSO, BRN-RP

FIRM: AcroMed Corp.
Cleveland, OH

SUBJECT: Investigation

Paula Ames
13400 Shaker Blvd.
Cleveland, OH
216-283-5571

FROM: Frederick M. Lochner
Investigator

Per verbal instructions from CIN-DO Compliance Officer Leonard Farr, I interviewed Paula Ames at her home on 9/10/91. I was accompanied by Investigator Susan C. Morgan. The interview involved activities at AcroMed Corp.

Ms. Ames no longer works at AcroMed. She was hired about October 1987 and fired about April 1988. She was the Director of Business Development. She said Ed Wagner fired her because he felt she was trying to take over the company. Most of her time was spent learning the firm's operations but she was involved with marketing and advertising of the firms products. Ed Wagner was her boss. Dr. Steffee did not come around the office very often. Ed Wagner was in charge of the operation of AcroMed.

* * * We discussed the booths AcroMed had at orthopedic conventions and seminars. Ms. Ames was one of the people

working at the booths. She said she was in training so did not deal with the people who came to the booths very much but did hand out materials that AcroMed provided to be passed out. Mr. Watermeier was the main spokesperson at the booths. Ms. Ames said he was in charge of the literature and materials available at the booth but Ed Wagner gave the orders as to what would be available and how it would be distributed. Mr. Taylor and other AcroMed people would also take turns at the booths. AcroMed took part in these conventions (bought the booth space) but did not sponsor the conventions.

Ms. Ames stated videotapes were available at the booths both for viewing and distribution. I showed her the titles of two videos ("The VSP System" and "Pedicular Fixation with VSP Plates"). She recognized them and thought they were the ones available at the booths. She did not remember a Technique Manual being available. I also showed her a series of reprints of journal articles. She said they looked like what was also available for distribution at the booths. She said they had a lot of material to hand out.

I asked if any of these handouts were stamped or marked to indicate the plates and screws were investigational devices if for use in the spine. She did not remember if such stamps were used or not. She said there was no doubt the plates and screws were for spine use. They never were intended for use on arms or legs.

Ms. Ames said they knew the plates and screws had not been approved for spine use. Mr. Watermeier was very aware of this. He stressed caution when promotion for spine use was involved. He was very nervous about using the videos. Ed Wagner was not nearly as cautious and pushed the distribution of the literature and use of the videotapes. He was ultimately responsible for the promotional materials used according to Ms. Ames.

We also discussed the seminars/training sessions where surgeons were taught how to implant the plates and screws on spines. Ms. Ames said she would sit in at these sessions to observe. Dr. Steffee would give lectures using slides and films and doctors would actually implant the devices. Literature and videos were also available to participants. She was not sure of AcroMed's actual involvement with the training sessions including if AcroMed sponsored or paid for them. She did not know where and when each was held.

* * * Ms. Ames said there was no doubt AcroMed was promoting and marketing the plates and screws for spine use. The employees knew they had not received approval for this use and were surprised not only about the prices charged but the large amount of sales. She said some people at AcroMed desired a conservative approach and were concerned about the legality of the promotional activities. These included Mr. Watermeier, Mr. Taylor and Terry (the engineer). Mr. Wagner preferred a more active approach and pushed the employees to actively promote the VSP system for spine use. He had the ultimate decision on how active the promotions would be. At times Mr. Watermeier would argue with Mr. Wagner over the distribution of the videos but Mr. Wagner controlled this and had the final say. Mr. Watermeier would try to put reins on the promotional activities but Mr. Wagner would go ahead and do whatever he wanted. * * * *

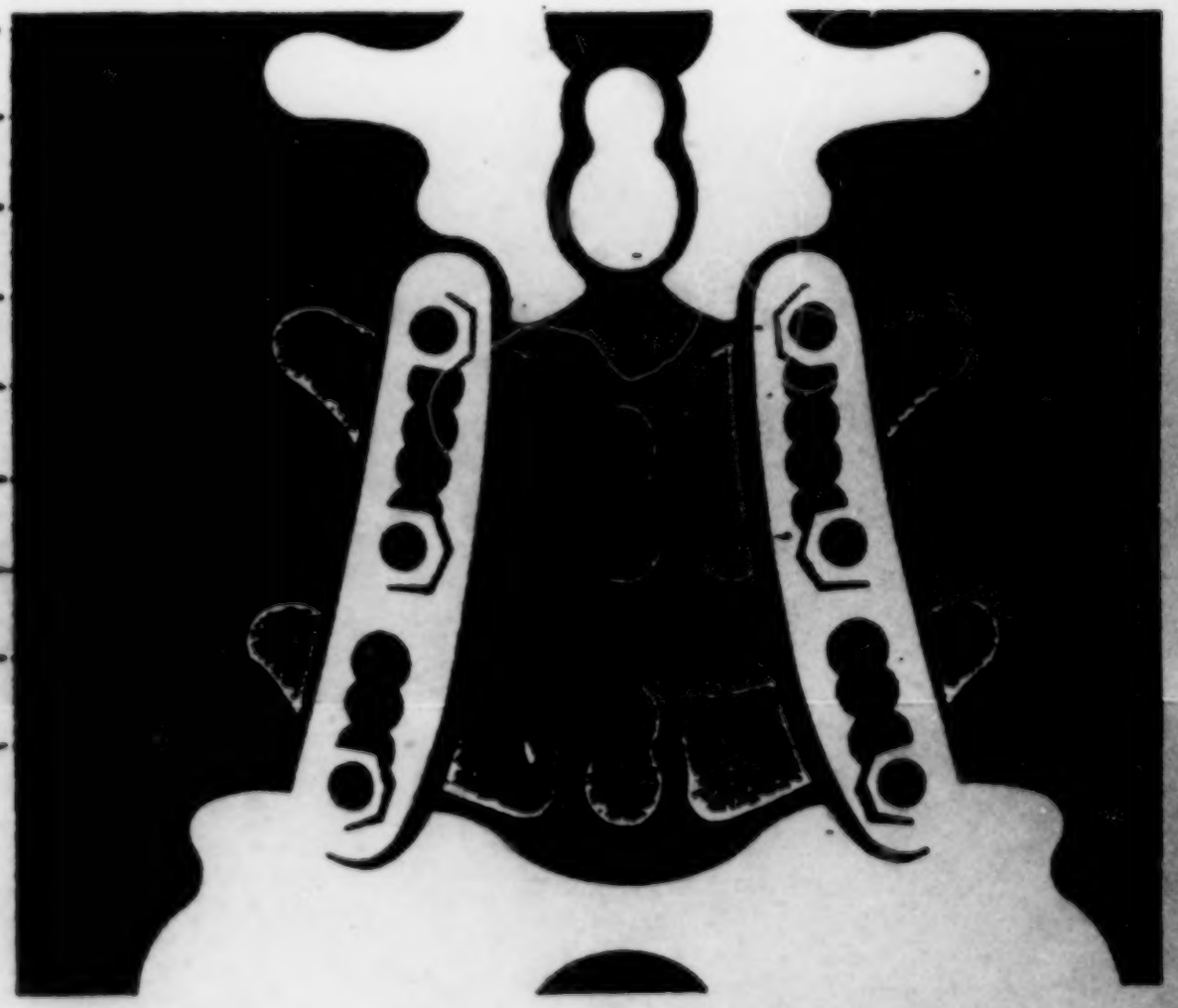
EXHIBIT 49

[See following inserted pages, which are redacted portions of exhibit]

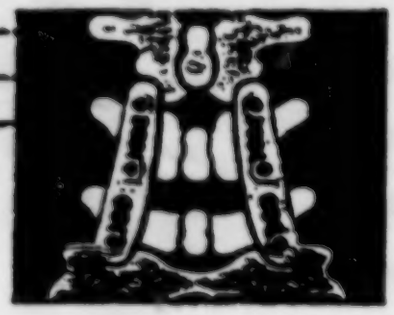
BEST AVAILABLE COPY

Assgn. FD-189
Roger M. Sobel, M.D.
1-24-90 TA/DLB
Exhibit 3.1

VSP Plating System Technique Manual



Assgn. FO-10a
Roger M. Sobel, M.D.
1-24-90 TA/DLB
Exhibit E.7.



Dear Colleague,

After attending a number of seminars, courses and scientific meetings that have dealt with the use of plates and screws for spinal alignment and stabilization, and after discussing with other surgeons who, like ourselves, have had some experience with these devices, we believe it would be helpful to set out some techniques and guidelines that we have found successful in our own surgical practices when we use such devices.

The contents of this manual are not adequate for complete instruction in the use of this system. Only a qualified surgeon who is skilled in spinal instrumentation and understands the biomechanics of the unstable spine should use this system. Lack of expertise in surgical stabilization of the unstable spine may result in avoidable complications.

Like everything else, these devices are not meant to address every spine related problem, rather they must be used with a great degree of care and skill, and must be buttressed by sound diagnostics and skillful aftercare.

It is our hope that this manual will be helpful as you develop your skill to the point that these plates and screws will become a regular part of your surgical armamentarium.

Arthur D. Steffee, M.D.
Cleveland, Ohio

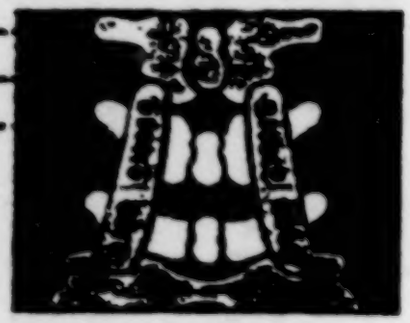
Louis Keppler, M.D.
Cleveland, Ohio

Roger A. Sobel, M.D.
1-24-90 TA/DLB
Exhibit

BACKGROUND

The VSP (Variable Screw Placement) Bone Plate and Bone Screw System may be used by surgeons to address any number of surgical situations (see primary indications) and was developed with an understanding of the concept of the "force nucleus" as an explanation of the dynamics of the forces and elements that interact to bring balance, form and structure. Applying this concept to the spine, it was determined that each motion segment has "two "force nuclei," through which five anatomical structures: the superior facet, the inferior facet via the pars interarticularis, the lamina, the pedicle and the transverse process, channel all posterior forces that are transmitted to the body.

The "force nucleus" of normal vertebrae is located at a point where the ridge of the pars, the ridge of the superior facet and the ridge of the transverse process converge (Fig. 1) Opening the cortical bone at this point offers the "force nucleus" a "window" into the intramedullary canal of the pedicle through which the screw passes into the body of the vertebra. (Fig. 2)



FORCE NUCLEUS OF VERTEBRAE

Fig. 1

Fig. 2

PRIMARY INDICATIONS

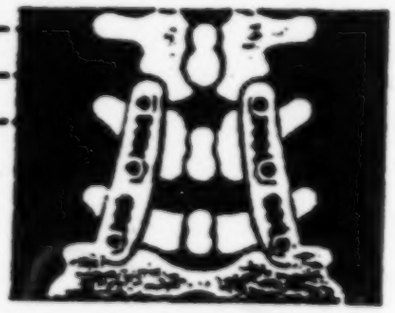
Use of the screws and plates are indicated in situations of spinal instability,* including:

- Spinal Trauma, including fractures
- Degenerative Spondylolisthesis
- Isthmus Spondylolisthesis
- Vertebral Body Arthroplasty
- Degenerative Disc Disease
- Adult Onset Scoliosis
- Paralytic Scoliosis
- Fixation of Vertebral Osteotomy
- Acquired Instability
- Tumors

Roger A. Sobel, M.D.
1-24-90 TA/DLB
Exhibit

CONTRAINDICATIONS

- History of Infection
- Bony abnormalities preventing safe screw fixation (dysplastic pedicles)
- Patients who have been shown to be safely and predictably handled without internal fixation
- Morbid Obesity
- Severe Osteopenic
- Open Wounds
- Metal Sensitivity
- Rigid Scoliotic Curves



SYSTEM COMPONENTS:

BONE SCREWS

The VSP Bone Screws are fabricated from 22-13-5 stainless steel, and are composed of two parts a long cancellous section with an integral fixed lower nut, and a machine threaded section topped with an hexagonal drive head.

The screws and plates are coloned utilizing a double nut locking system. The screw features an integral fixed lower nut that is machined directly from the same piece of metal stock. (Fig. 3)

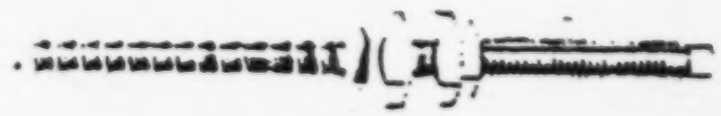


Fig. 3

IMPLANTABLE PLATES

The VSP Bone Plates are fabricated from 316 LVM implant grade stainless steel. The plates have nested slots and variable lengths to span the vertebral levels to be stabilized. The plates have between one to five slots. (44 mm to 196 mm length) with their length increasing by half slot increments. Longer plates are available as special order items.

The slots, with their precisely machined tapered nests, offer the possibility of accurate yet variable screw placement along the spinal column. It is important that the plates be bent in a plate bender to mirror or to create the desired sagittal curve of the spine.

Use the shortest plate possible for each procedure. Minimal plate length will reduce the possibility of plate interference with any uninvolved facet joints. (Fig. 4)

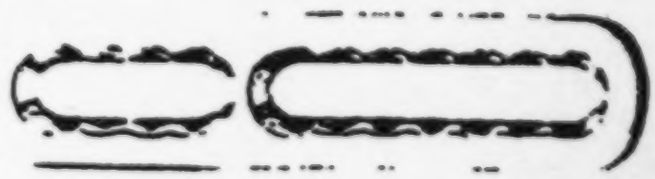


Fig. 4

BEST AVAILABLE COPY

[Exhibits 50-51 omitted]

EXHIBIT 52

AcroMed Corporation
3303 Carnegie Ave.
Cleveland, Ohio 44115
216/431-9900

TO: Physicians Utilizing VSP Bone Plates and Screw System
FROM: AcroMed Corporation
DATE: September 1, 1987
RE: Patient Consent Form

We have been asked over the past several months by a number of surgeons for information about a Patient Consent Form for use when performing procedures utilizing various spinal implant devices. It occurred to us that others may be asking the same question.

As a courtesy service, we have asked our legal counsel to draft an appropriate consent form, and he has produced the enclosed draft.

You may want to compare the Patient Consent Form you are now using and determine which may be better, i.e., adopt only some of the language and terms, delete others, but make as certain as possible that you have the best form you can. As you are aware, informed consent by a patient entails more than just signing a form. The items in the consent form must be discussed with and explained thoroughly to the patient in order for the consent to be effective.

Since we are not in the business of providing legal advice, the enclosed draft is offered to you without recommendation, but as a courtesy to share information that you and your legal counsel may find helpful.

Edward J. Wagner
President & CEO

[Exhibits 53-84 omitted]

EXHIBIT 85
IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

[Caption omitted]

SUPPLEMENTAL DECLARATION OF
CARL A. LARSON, PH.D.

I hereby declare:

1. My duties as Director of the Office of Surgical and Rehabilitation Devices from October of 1979 through January of 1992 included supervising the evaluation of devices submitted for 510(k) substantial equivalence determination as well as Pre-Market Approval evaluations.

2. When a device manufacturer submits a device for a 510(k) substantial equivalence determination, the only thing the device is reviewed for by the FDA reviewers is for its "substantial equivalence" to a device with the same intended use and substantially similar technological characteristics (design and materials) and application to a device in use prior to adoption of the Medical Device Amendments. As set forth more fully in my Declaration of November 26, 1994, the Medical Device Amendments came into effect in 1976.

3. The 510(k) notification process only provides for the FDA to review the submitted devices to determine whether they are "substantially equivalent" to existing devices, which means equivalent in intended use and technological characteristics and, further that the device does not raise new safety and effectiveness questions for its intended use.

4. In reviewing a 510(k) submission, the FDA does not make any determinations whatsoever relating to the sufficiency of labeling nor the safety and effectiveness of the submitted device. Although proposed labeling and often times test results are submitted with the 510(k) application, they are not evaluated for their sufficiency or for the device's safety and effectiveness.

5. The FDA did make a determination in November of 1985 that AcroMeds VSP Pedicle Screw device was not substantially equivalent to a pre-amendment device for use in the pedicles of the spine and, therefore, as a Class III significant risk investigational device, required proof of its safety and effectiveness through the Pre-market Approval (PMA) Process.

6. The manner in which Class III devices, such as pedicle screws, are reviewed for determinations of safety and effectiveness and sufficiency of labeling is through the PMA Process. As part of the PMA process, the FDA comprehensively evaluates the device, the sufficiency of its labeling and the safety and effectiveness of the device through detailed prospective clinical trials which are closely monitored and evaluated by the FDA both during and after the actual trials are conducted. Not only is AcroMed's VSP device for use in the pedicles of the spine a Class III significant risk investigational device, it is also considered a critical device by the FDA. A critical device requires even greater GMP controls and tracking procedures than other Class III devices. (See Scarlett Affidavit paragraphs 62-64, attached as an exhibit to AcroMed's Brief).

7. AcroMed then reapplied for 510(k) substantial equivalence determination for certain limited components of its previously submitted VSP device and disengenuously indicated to the FDA its use as a fixation device for fractures of long bones, a Class II moderate risk use (See Declaration of Carl Larson, November 26, 1994 paragraphs 41-43).

8. A 510(k) substantial equivalence determination is not tantamount to an approval of a device or its labeling. It was merely an attempt by the legislature to provide a level playing field for

newer manufacturers or manufacturers with substantially equivalent devices (in design characteristics and application) to those devices that had been in distribution and use prior to the adoption of the Medical Device Amendments.

9. The limited labeling review that does occur with a 510(k) substantial equivalence determination is reviewed only for the intended use that the device is submitted for pursuant to the 510(k). The FDA makes absolutely no determination of the safety and effectiveness of the device or the sufficiency of the labeling for any "off label" use(s).

10. Funding is extremely limited at the FDA, and the agency and its representatives are forced to make decisions regarding compliance and enforcement which take funding considerations into account.

11. Oftentimes, the agency will choose not to prosecute or vigorously pursue manufacturers despite evidence, as with the pedicle screw manufactures, that they are illegally promoting and marketing a device for off label use. Simply because the agency becomes aware that a device is being marketed and promoted for an off-label use, and doesn't act to ban the sale of the device or recall the device, in no way reflects the FDA's approval of the off-label use of that device nor the manufacturers' illegal promotional and marketing tactics.

12. Such action or inaction by the FDA is no more than a recognition of the realities of limited funding and an inability to fully police a rapidly expanding market.

13. Although sometime in 1987 the FDA was made aware of the fact that there were manufacturers who were marketing and promoting pedicle screw devices for off label use, the FDA was not aware of the widespread abuses and the extent of promotional and marketing activities which have become apparent to me from reviewing documents produced by AcroMed in this litigation.

14. The FDA was also unaware of the full extent of device failure complications and injuries caused by pedicle screw devices,

due to the manufacturers' failure to comply with the reporting requirements of the Medical Device Amendments and the Medical Device Reporting Act. It is my opinion that there was a further attempt to conceal the extent of the problem from the FDA.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 27 day of May, 1985.

/s/_____
Carl A. Larson, Ph.D., P.E.

[Remaining numbered exhibits omitted]

APPENDIX OF DEPOSITIONS

DEPOSITION OF SETH A. GREENWALD

* * * [68] Q. Did all of the patents that pertain to this pedicle screw and plate project that you
[69] worked on with Dr. Steffee pertain to spinal fixation?
A. Again, Mr. Eaton, I'd have to review the patents.

The intended application, when we first began developing the pedicle screw and spine plate at Cleveland Research Institute, was intended to be used as a spinal fixation device.

I do not recall if the actual patent application indicated a specific spinal application, although I believe the subsequent one did that emerged. There have been several, actually.

I'd have to review – I mean, it's not fresh in my mind at the moment.

Q. Okay. The work you did with Dr. Steffee with respect to his pedicle screw and plate system, in the time you worked on that project, was there any effort given or investigation done with respect to an intended use involving long bone or flat bone fixation?
A. That was not why we undertook the project.

There are a number of devices
[70] readily available for fracture or fixation of long bones.

This had a specific intended application at the time of our undertaking, and it was to be used for spinal fixation.

Q. Does that mean you did no work with respect to design or development of this system for long bones or flat bones?

A. That is correct. * * * *

[Other Depositions omitted]

IN THE UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF PENNSYLVANIA

[Caption omitted]

Plaintiffs' Memorandum in Opposition
to Defendant AcroMed Corp.'s Motion
to Reaffirm PTO 12 in Light of
Medtronic, Inc. v. Lohr

Filed December 2, 1996

[Text of Memorandum and Exhibits 1 and 2 omitted]

EXHIBIT 3
[Deposition Testimony of Arthur D. Steffee, M.D., 5-2-96]

[59] [Q:] The purpose of pedicle screws is to temporarily stabilize the spine to assist in fusion; is that right?

[60] A. Correct.

Q. And there are other ways to stabilize — to try to stabilize the spine without using pedicle screws, right?

A. You can use a cast. You can use older methods, Harrington Rods and things like that, but I don't use them.

Q. Why don't you use those?

A. Because the screws are better. * * *

[Exhibits 4-7 omitted]

EXHIBIT 8
IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: ORTHOPEDIC BONE : MDL DOCKET NO. 1014

SCREW PRODUCTS :
LIABILITY LITIGATION :

DECLARATION OF CARL LARSON, PH.D., P.E.

I, Carl Larson, Ph.D., P.E., declare:

1. I served as Director for the Division of Surgical and Rehabilitation Devices (DSRD) of the United States Food and Drug Administration from October of 1979 through January of 1992. Beginning in January of 1992, I retired and have worked privately as a Medical Device Regulatory Consultant. * * *

3. During my twelve years with the Food and Drug Administration, I was intimately involved in the management of the regulatory process pertaining to the pedicle screw manufacturers of internal spinal fixation devices utilizing pedicle screws ("pedicle screw devices"), specifically including Acromed Corp. ("Acromed"), Sofamor, S.N.C. ("Sofamor"), Danek Medical Company, and many others and I was responsible for many of the ultimate regulatory decisions made by the FDA concerning pedicle screw products.

4. I am making this declaration in support of class certification because, as I will explain in greater detail, these corporations and the medical device industry have actively promoted pedicle screw devices in derogation of the Medical Device Amendments to the Food, Drug and Cosmetic Act, and in reckless disregard for the fact that they have never been able to demonstrate with scientifically valid data or evidence that these devices were safe or effective for spinal fusion surgery.

5. The primary purpose of the Medical Device Amendments to the Food, Drug and Comestic Act, and the principal goal of my division with the FDA, was to ensure that medical devices were demonstrated to be safe and effective for their intended use **before** they were marketed. * * *

28. All of the FDA's clearance and classification decisions are based upon the intended use of the device as represented to us by the manufacturer or device proponent. If the device is promoted for a use other than that which is represented to be its intended use and which serves as a basis for Pre-Market Approval or 510(K) clearance, then that device is considered misbranded or adulterated in violation of federal law.

29. The FDA's position on pedicle screw devices has consistently been that these devices are significant risk Class III investigational devices which require an IDE and Pre-Market Approval. There has never been sufficient safety and efficacy data provided to allow such approval.

30. As of the present date, no pedicle screw manufacturer has been able to successfully complete a clinical trial under an IDE which has led to Pre-Market Approval of any pedicle screw device. Accordingly, there are no legally marketed pedicle screw devices in this county at present, nor has there ever been any demonstrated to be reasonably safe and effective for pedicle fixation.

31. The FDA's position regarding these devices was further set forth in a letter directed towards the American Academy of Orthopedic Surgeons dated July 13, 1993, in which the FDA stated.

> In this case the Medical Device Amendments are clear in language and intent. New intended uses and new devices pose a potentially significant risk to patients and are automatically classified as Class III devices and may only be marketed (and promoted for new uses) after agency approval of a Pre-Market Application (PMA). Since 1984 FDA has repeatedly informed sponsors of such products of the classification status and the conditions under which these new devices could be clinically investigated to determine their safety and effectiveness. Beginning in 1988, FDA has further notified sponsors of screw and plate medical device products submitted through the 510 (k) process of the classification of vertebral pedicle screws, limitations imposed on labelling, promotion and marketing for

devices such as bone screws, inter-vertebral body screws, sacral screws, iliac screws, bone plates, and spinal fixation systems incorporating bone screws. These 510 (k) letters now also include notice of what would constitute adulteration or misbranding of approved devices.... In sum, there are no legally marketed bone plates, bone screws, spinal screws, pedicle screws, or device systems that incorporate bone screws commercially available in the United States, that have been cleared or approved for spinal fixation when used for attachment through the pedicle of a vertebra. PMA's have been submitted for such products but FDA has refused to accept them for filing because of patient inadequacies in the applications including insufficient follow up of patients, statistically inadequate sample sizes, lack of defined clinical justifications for patient entry. Lack of valid controls and lack of discernible end points. Pedicle screw spinal fixation device systems are currently limited to commercial distribution as part of experimental protocols in over seventeen ongoing studies under the Investigational Device Exemption (IDE) provisions of the Medical Device Amendments.

32. In 1983, Dr. Arthur Steffee patented a device known as the VSP Spinal Fixation System. This device was commercially produced by Acromed Corporation, and designed as an internal spinal fixation device involving plates to be attached to the spine by means of the insertion of bone screws into the pedicles of the vertebrae.

33. In September of 1984, Acromed submitted a 510 (k) Notification to the FDA notifying us of the intent to market the VSP Spinal Fixation System as a device which was substantially equivalent to devices already on the market. See 510 (k) Notification Letter attached as Exhibit "B".

34. In December of 1984, the FDA notified Acromed that the device could not be found substantially equivalent to any predicate device because of insufficient information, and offered to reevaluate

the 510 (k) Notification if Acromed would submit additional data pertaining to safety and efficacy for its intended use. See letter from the FDA attached hereto as Exhibit "C".

35. Acromed submitted some additional information in September of 1985, which the FDA reviewed.

36. In November of 1985, the FDA notified Acromed that the device was determined to be not substantially equivalent (NSE) for its intended use. Moreover, we informed Acromed that the device was classified as a Class III significant risk investigational device, and that the device posed "potential risks (new types of safety and effectiveness concerns) not exhibited by other spinal fixation systems, such as:

(a) Greater chance of neurological deficit due to imprecise screw placement and in the event of screw failures;

(b) Pedicle fracture during placement of the screw;

(c) Soft tissue damage or inadequate fusion due to bending or fracture of device components; and

(d) Greater risk of pseudarthrosis due to instability of design."

See letter from the FDA attached hereto as Exhibit "D".

37. On December 12, 1985, a meeting was held in my office at the FDA where I was present together with Ken McDermott, Dan McGunagle and Tom Callahan from the FDA staff and Joe Radzius, Arthur Steffee, Ed Wagner and Pamela Buckman, from Acromed Corporation. The meeting was requested by Acromed to take issue with the FDA's determination that the VSP Spinal Fixation System was not substantially equivalent to any predicate device for pedicle screw fixation. At that meeting we reiterated to the Acromed representatives the four new safety and effectiveness concerns which the VSP Spinal Fixation System presented which were not present with the devices claimed to be "predicate devices" by Acromed Corporation as outlined in paragraph 36 above. We informed Acromed's representatives that premarket approval, based upon data derived from a clinical trial conducted pursuant to an appropriate

IDE was required before the VSP device could be marketed because of these new safety and efficacy concerns.

38. At this meeting, Acromed's representatives inquired as to whether the company could train surgeons in the use of the VSP device for pedicle screw fixation. In response, the FDA's representatives explicitly and specifically told Acromed's representatives that they could only train surgeons in the use of the device after an IDE was submitted and approved and could train no one other than the approved clinical investigators and only for implantation in approved clinical trials pursuant to IDE approval.

39. At no time during that meeting, or at any other meeting of which I am aware, did the FDA ever suggest that Acromed seek approval for the VSP system of plates and screws as "bone plates" and "bone screws." Acromed did raise the questions of whether it could label and sell the device as "bone plates" and "bone screws" and were told that it would have to submit separate 510 (k) applications for these purposes and that the FDA would evaluate those applications individually.

40. It was clear that if Acromed submitted separate 510 (k)'s for the use of the VSP device as a "bone plates" or "bone screws" it would have to be for the limited use defined in the FDA orthopedic devices classification category 21 CFR 888.3030, for fixation and fusion of long bones and flat bones only.

41. In December of 1985, Acromed submitted a new 510 (k) Notification for a device named the "Acromed Nested Bone Plate", and separate 510 (k) notification for a device known as a "Cancellous Bone Screw". Upon review of the technological characteristics (design and materials) for these devices, it was clear that they were identical in all technological characteristics to the components of the VSP Spinal Fixation System. In fact, one of my staff reviewers, Ken McDermott, noted this similarity in an internal memorandum which is attached hereto as Exhibit "E". Mr. McDermott requested further information from Acromed concerning the intended use of these devices.

42. In January of 1986, in direct response to questioning from the FDA, Acromed wrote and represented that these bone plates and bone screws were intended for use "in appropriate fractures of long bones of both the upper and lower extremity...", which is in complete agreement with the classification under 21 C.F.R. 888.3030.

See letter from Acromed representatives attached hereto as Exhibit "F".

43. After considering Acromed's 510 (k) applications for the "Nested Bone Plate" and "Cancellous Bone Screw", and in direct reliance upon Acromed's representation that these devices were intended for use solely in fractures of long bones in both the upper and lower extremities, the FDA issued a finding of substantial equivalence for these devices, and they were designated as Class II devices for that specific use pursuant to 21 C.F.R. 888.3030. As such, they were permitted to be commercially distributed for use in the long bones of the arms and legs. This finding can in no way be construed as permitting use of the Acromed bone screws and bone plates in the pedicles of the spine for spinal fusion procedures. Inherent in the FDA's decision and in the classification of the device, was the limitation imposed upon us at the FDA by Acromed representing in writing that the device was intended for use solely in healing fractures of the long bones. Obviously, the potential for serious injury to a patient is far greater when this device is inserted in the pedicles of the spine, millimeters away from the central nervous system and nerve roots, than the potential for injury when the device is inserted into a tibia or femur. Thus, with the risk factor being so reduced, and the fact that orthopedic surgeons have long used screws and plates in fusions of long bones, the FDA had little choice but to consider this device as substantially equivalent to devices already on the market for these intended uses.

44. There can be no question that Acromed misrepresented the intended use of the device. Indeed, I have even seen testimony from Acromed's own Corporate Designee admitting that, in fact, there

were no known clinical uses for these devices other than pedicle screw fixation in spinal fusion procedures, even though the devices were shipped to hospitals with appropriate packaging and labelling, limiting approved use of the devices to fixation of long bones. See Notes of Testimony attached hereto as Exhibit "G".

45. In addition, there is no question that Acromed actively labeled and promoted its bone plates and screws exclusively for use in spinal fixation procedures involving the insertion of screws within the human pedicles. Among other things, Acromed published a catalog describing and depicting its bone plates and screws as "transpedicular screws" and "spine plates." See Exhibit "H". Acromed encouraged spine surgeons to ignore the approved labelling and use its plates and screws in an unapproved manner in spinal fusion procedures. Acromed rewarded the surgeons by appointing them to its Medical Advisory Board, furnishing the surgeons with lucrative stock options through which they could participate in the financial growth of the company and the anticipated public offering of its stock and paying their expenses for attending meetings and symposia at which physicians were instructed in spinal instrumentation techniques using the VSP device. See Exhibit "I". Moreover, Acromed apparently prepared a booklet for spine surgeons to provide to their patients which promoted the use of VSP implants and screws in back operations. See Exhibit "J". In addition, Acromed created and disseminated to physicians a "Techniques Manual" which demonstrated the use of its plates and screws exclusively in spinal pedicle fixation procedures. See Exhibit "K". **Because the FDA never cleared or approved Acromed's bone plates and screws for any spinal applications, all of these activities by Acromed constituted misbranding and adulteration of the devices in violation of federal law**. It is my understanding that there is presently a grand jury investigation proceeding in the Southern District of Ohio investigating these charges.

46. Acromed substantially altered the design and materials of its bone plates and bone screws on at least four separate occasions

and never made additional 510 (k) applications as required by the FDA regulations each time there is a change in the design or materials of a device originally cleared by the FDA under the 510 (k) process.

47. One such example of Acromed's changing the design was the introduction of the integral nut to the screw. The December, 1985 application which Acromed submitted to the FDA for Section 510 (k) clearance to market "cancellous bone screws" related to bone screws did not have an integral nut as part of the described screw design. Bone screws with integral nuts could not be used in the repair of fractures of the long bones and could not be considered substantially equivalent to cancellous bone screws then present on the market. However, in 1986 Acromed changed the design of the cancellous bone screws to include an integral nut. Acromed never submitted an application for premarket approval with respect to this integral nut screw nor did it submit any 510 (k) notifications for this device. Since Acromed's integral nut screw was a new device which did not receive premarket approval and which was not cleared for marketing pursuant to the 510 (k) notification process, it could not be legally marketed by Acromed or used by physicians at all. Nonetheless, virtually all of the screws sold by Acromed for use with its nested bone plates were screws incorporating the integral nut design. Thus, all of the surgeries performed outside of the IDE clinical trials involving Acromed's plates and screws were performed in violation of federal law.

48. In January, 1986, Acromed applied for an investigational device exemption to study the VSP Spinal Fixation System. After submission of all of the required data, the IDE was approved and limited clinical trials were permitted to commence.

49. The sponsor/manufacturer is required as part of its IDE application to submit to the FDA the cost of the device and is not permitted to charge any more for the device than the costs of manufacture plus research and design costs. The cost of the device

must adhere to the IDE Rules which prohibit the manufacturer from making any profit on the sale of the device.

50. Prior to April of 1990, FDA inspectors gathered evidence and submitted it to the FDA Office of Compliance, General Counsel and Office of the Commissioner leading to the FDA's termination of Acromed's clinical trials and revocation of its Investigational Device Exemption for the VSP Spinal Fixation System because inspections of the investigational sites and the investigators' records revealed numerous and gross violations of the approved clinical protocol. Specifically, the FDA found that Acromed, the IRB's and its investigators were severely negligent in the monitoring and conduct of the clinical trials resulting in failure to maintain accurate data, failure to conduct adequate follow up on patients, failure to obtain appropriate informed consent from patients, and failure to report all adverse incidents related to the device. These patients were only a small percentage of those actually being implanted with the devices. Therefore, in an effort to protect the public health, in April of 1990 the FDA revoked Acromed's clinical trials for its VSP plates and pedicle screws, without granting the company an opportunity for a hearing because it was determined that the risk to the public health was so great. See letter from FDA to Acromed attached as Exhibit "L".

51. There has been absolutely no data ever submitted to date by Acromed or any other manufacturer, nor any data available through the literature or elsewhere, sufficient to satisfy the FDA's concerns regarding the four new safety and efficacy questions.

*** I declare under penalty of perjury that the foregoing is true and correct.

Executed on this 26th day of November, 1994.

/s/
Carl Larson, Ph.D., P.E.

[Exhibit A to Declaration of Carl A. Larson, Ph.D., omitted]

Exhibit B to Declaration of Carl A. Larson, Ph.D.

Buckman Company, Inc.
921 Calle Verde
Martinez, California 94551
(415) 972-7740

September 4, 1984

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
8757 Georgia Avenue
Silver Spring, MD 20910

Dear Document Control Clerk: 510K – NOTIFICATION

The attached information is submitted in accordance with Part 807, Subpart E of the code of Federal Regulations Chapter I, Title 21.

It is our opinion that the "Variable Screw Placement" (VSP) Spinal Fixation Plating System is substantially equivalent to devices manufactured and marketed prior to May 28, 1976. We conclude that the following information supports our position.

We further believe that some of the information included herein is of a confidential nature. Neither the manufacturer nor I have any knowledge of the release of this information to any party other than the recognized employees or agents of AcroMed Corporation. We agree to notify the Food and Drug Administration when a change

in this situation occurs. Until then we suggest that this document not be released through FOI requests or any other way.

As the official correspondent for AcroMed Corporation for this product line, please direct any correspondence relative to it to my attention at the address indicated for Buckman Company, Inc.

We thank you in advance for your prompt consideration of this submission and will be happy to provide additional information as you may require.

Sincerely,

/s/
Pamela M. Buckman, R.N., M.S.

PMB/ds
cc: Edward Wagner, AcroMed Corporation
Enclosure: 510K Notification (3 copies)

Exhibit C to Declaration of Carl A. Larson, Ph.D.

Department of Health & Human Services
Public Health Service
Food and Drug Administration
8767 Georgia Avenue
Silver Spring, MD 20910

[Date-stamped: December 19, 1984]

Re: K843600
Variable Screw Placement (VSP)
Spinal Plate Fixation System
Regulatory Product Class: III
Dated: September 4, 1984
Received: September 12, 1984

Ms. Pamela M. Buckman,
R.N., M.S.
Buckman Company, Inc.
921 Calle Verde
Martinez, California 94553

Dear Ms. Buckman:

We have reviewed your Section 510(k) notification of intent to market the above device and we have determined that the information is your submission does not demonstrate that your device is substantially equivalent to one marketed in interstate commerce prior to May 28, 1976, or to any device which has been reclassified into class I (General Controls) or class II (Performance Standards). This decision is based on the fact that immobilization of the spinal column by means of an intervertebral fixation plate with specifically-designed screws in the manner that you propose to achieve spinal fusion and correct various spinal conditions (such as adult onset scoliosis and spondylolisthesis) was not in use before May 28, 1976, and that insufficient data documenting the safety and effectiveness of the VSP Spinal Plate Fixation System were submitted. We may re-evaluate this determination if you provide:

(a) data establishing that the specially-designed screws and plate fixation system are capable of withstanding dynamic simulation tests under worst-case loading conditions which are representative of the actual use, in-vivo conditions; and

(b) data and results from a clinical study including several investigators which has sufficient number of patients and duration to document the long-term safety and effectiveness of the VSP Spinal Plate Fixation System for each proposed indication of use (i.e., adult onset scoliosis and spondylolisthesis).

Therefore, your device is classified by statute in class III (Premarket Approval), under Section 513(f) of the Federal Food, Drug, and Cosmetic Act (Act).

Section 515(a)(2) of the Act requires class III devices to haves approved premarket approval application (PMA) before they can be legally marketed unless the device has been reclassified.

Premarket Approval. To prepare a premarket approval application, statutory provisions appearing in Section 515(c) of the Act must be followed. To assist you in preparing a PMA, we have enclosed a copy of the proposed PMA procedures regulation and a "Guideline for the Arrangement and Content of a PMA."

Investigational Use. In the absence of an approved premarket approval application, a class III device may be distributed only for investigational use. Enclosed is a copy of the investigational device exemption regulation, which must be followed if your devices are used in a clinical investigation.

Petition for Reclassification. If you believe that your devices should not have to undergo premarket approval before they are commercially distributed, you may petition FDA for reclassification of your devices under Section 513(f)(2) of the Act.

Premarket approval applications, investigational device exemption requests, and petitions for reclassification should be submitted to:

Food and Drug Administration
Office of Device Evaluation
Document Mail Center (HFZ-401)
8757 Georgia Avenue
Silver Spring, Maryland 20910

Any commercial distribution of this device prior to approval of an application for premarket approval or the effective date of any order by the FDA reclassifying your device into class I or II, would be a violation of the Act. Clinical investigations of your device must be in accordance with the investigational device exemption regulation.

If you have additional information that may alter this decision or if you need any information concerning our decision or the alternatives available to you under the law, please contact James G. Dillon, Ph.D., at (301) 427-7238.

Sincerely yours,

/s/
Robert G. Britain
Director
Office of Device Evaluation
Center for Devices
and Radiological Health

Enclosures

Exhibit D to Declaration of Carl A. Larson, Ph.D.

Department of Health & Human Services
Public Health Service
Food and Drug Administration
8767 Georgia Avenue
Silver Spring, MD 20910

DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
8767 Georgia Avenue
Silver Spring, MD 20910

Ms. Pamela M. Buckman, R.N., M.S.
Buckman Company, Inc.
921 Calle Verde
Martinez, California 94553

Re: K853913
Variable Screw
Placement (VSP)
Spinal Plate Fixation
System
Dated: September 20, 1985
Received: September 23, 1985

Dear Ms. Buckman:

We have reviewed your Section 510(k) notification of intent to market the above device and we have determined the device is not substantially equivalent to devices marketed in interstate commerce

prior to May 28, 1976, or to any device which has been reclassified into class I (General Controls) or class II (Performance Standards). This decision is based on the fact that there has not been adequate demonstration that there was a pre-amendment device labeled, advertised, or otherwise promoted, with a design substantially equivalent to the VSP Spine Plate System and on the fact that it poses potential risks not exhibited by other spinal fixation systems, such as:

1. greater chance of neurological deficit due to imprecise screw placement or the event of screw failure;
2. pedicle fracture during placement of screw;
3. soft tissue damage or inadequate fusion due to bending or fracture of device components; and
4. greater risk of pseudoarthrosis due to instability of design.

Therefore, your device is classified by statute in class III (Premarket Approval), under Section 513(f) of the Federal Food, Drug, and Cosmetic Act (Act).

Section 515(a)(2) of the Act requires class III devices to have an approved premarket approval application before they can be legally marketed unless the device has been reclassified.

Premarket Approval. To prepare a premarket approval application (PMA), statutory provisions appearing in Section 515(c) of the Act must be followed. To assist you in preparing a PMA, we have enclosed a copy of the proposed PMA procedures regulation and a "Guideline for the Arrangement and Content of a PMA."

Investigational Use. In the absence of an approved premarket approval application, a class III device may be distributed only for investigational use. Enclosed is a copy of the investigational device

exemption regulation, which must be followed if your device is used in a clinical investigation.

Petition for Reclassification. If you believe that your device should not have to undergo premarket approval before it is commercially distributed, you may petition FDA for reclassification of your device under Section 513(f)(2) of the Act.

Premarket approval applications, investigational device exemption requests, and petitions for reclassification should be submitted to:

Food and Drug Administration
Office of Device Evaluation
Document Mail Center (HFZ-401)
8757 Georgia Avenue
Silver Spring, Maryland 20910

Any commercial distribution of this device prior to approval of an application for premarket approval or the effective date of any order by the FDA reclassifying your device into class I or II, would be a violation of the Act. Clinical investigations of your device must be in accordance with the investigational device exemption regulation;

If you need any information concerning our decision or the alternatives available to you under the law, please contact Thomas J. Callahan, Ph.D., at (301) 427-7156.

Sincerely yours,

/s/
Kshitij Mohan, Ph.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

Exhibit E to Declaration of Carl A. Larson, Ph.D.

Department of Health & Human Services
Public Health Service

MEMORANDUM

Date:

From: Reviewer(s) – Name(s) Ken McDermott

Subject: 510(k) NOTIFICATION – K855224

To: THE RECORD

It is my recommendation that the subject 510(k) Notification:

_____ (A) Is substantially equivalent to marketed device.s

_____ (B) Requires premarket approval. NOT substantially equivalent to marketed devices.

__x__ (C) Requires more data.

_____ (D) Is an incomplete submission. (See Submission Sheet).

Additional Comments:

[Handwritten: This same implant was submitted in K853913 for spinal fixation and was NSE. The firm resubmitted the device here, without the screws and nuts which were included in K853913, for use as a common bone plate. I requested a list of indications from Mr. Schlerf 1/10/86.]

The submitter requests: Class Code w/Panel:

_____ No Confidentiality _____

_____ Confidentiality for 90 days

__X__ Continued Confidentiality exceeding 90 days

REVIEW:

(BRANCH CHIEF) (DATE)

FINAL REVIEW:

(DIVISION DIRECTOR) (DATE)

[Exhibit F to Declaration of Carl A. Larson, Ph.D. omitted]

Exhibit G to Declaration of Carl A. Larson, Ph.D.

DEPOSITION TESTIMONY OF GEOFFREY J. PORTER
Robert Baker v. Donald L. Myers, et al., March Term 1990
No. 4915 (Ct. Com. Pls. Phila. Cty.)

[17] * * * Q. So, am I correct based on your earlier testimony that the only place through where these plates are actually designed for use is the spine?

A. That is correct. * * *

Exhibit H to Declaration of Carl A. Larson, Ph.D.

[See following inserted pages, which are redacted portions of exhibit]

No. 6861

AcroMed® PRICE LIST

Effective June 1, 1986

BEST AVAILABLE COPY

Supersedes all previous price lists.
Please dispose of all previous price lists.

VSP SPINE PLATES

Order No.	Description	Unit Quantity	Price
2025-01*	VSP Spine Plate - 1 Slot	2	625.00
2025-01.5*	VSP Spine Plate - 1.5 Slot	2	650.00
2025-02*	VSP Spine Plate - 2 Slot	2	675.00
2025-02.5*	VSP Spine Plate - 2.5 Slot	2	700.00
2025-03*	VSP Spine Plate - 3 Slot	2	725.00
2025-03.5*	VSP Spine Plate - 3.5 Slot	2	750.00
2025-04*	VSP Spine Plate - 4 Slot	2	800.00
2025-04.5	VSP Spine Plate - 4.5 Slot	2	850.00
2025-05	VSP Spine Plate - 5 Slot	2	900.00

VSP BUTTRESS CLAMPS

2025-10*	VSP Sacral/Buttress Clamp - 30° Under	2	90.00
2025-11*	VSP Sacral/Buttress Clamp - 45° Under	2	90.00
2025-12*	VSP Sacral/Buttress Clamp - 30° Over	2	90.00
2025-13*	VSP Sacral/Buttress Clamp - 45° Over	2	90.00

PLATE SPACER WEDGE

2025-15*	Plate Spacer Wedge	1	6.00

*Recommended for intial order
U.S. and foreign patents pending

VSP TRANSPEDICULAR AND SACRAL SCREWS

Order No.	Description	Unit Quantity	Price
2026-20*	VSP Sacral Screw	2	150.00
2026-22	VSP Transpedicular Screw	2	150.00
2026-24*	VSP Transpedicular Screw	10	750.00
2026-28	VSP Transpedicular Screw	10	750.00
2026-32*	VSP Transpedicular Screw	10	750.00
2026-34	VSP Transpedicular Screw	1	85.00

SCREW NUTS

2026-1000	3/8 in. Screw Nut	1	3.00
2026-1100	5/16 in. Lock Nut	1	2.00

*Recommended for intial order
U.S. and foreign patents pending

VSP SPINAL SURGERY INSTRUMENTS

Order No.	Description	Unit Quantity	Price
2025-4000	Basic VSP Instrument Set (See below)		1,094.00
2025-40	Screw Wrench with Hex Socket, T-Handle	1	50.00
2025-41	Tapered Nut Wrench, T-Handle with Hex Socket	1	65.00
2025-4100	3/8 in. Open End Nut Wrench	1	45.00
2025-4101	3/8 in. Nut Driver with Jacobs Shank	1	55.00
2025-42	Lock Nut Wrench, T-Handle	1	65.00
2025-4201	Lock Nut Driver with Jacobs Shank	1	55.00
2025-70	VSP Bone Tap - for 5.5mm Screw	1	95.00
2025-72	VSP Bone Tap - for 6.25mm Screw	1	95.00
2025-74	VSP Bone Tap - for 7.0mm Screw	1	95.00
2025-45	Screw Alignment Bar	1	75.00
2025-46	Screw Alignment Rods set of 2		40.00
2025-47	VSP Pedicle Probe	1	95.00
2025-48	VSP Plate Contouring Templates Set of 4		25.00
2025-49	VSP Pedicle "Sounder"	1	140.00
2025-50	VSP Intervertebral Spacer Wedges, Set of 3		370.00
2025-51	VSP Impactors Set with Quick Release Handle and Case		1,490.00
2025-52	Spinal Elevators ("Persuaders") Set of 2		225.00
2025-53	Foraminal Probes Set of 6		490.00
2025-54	Pedicle Locator		9.00

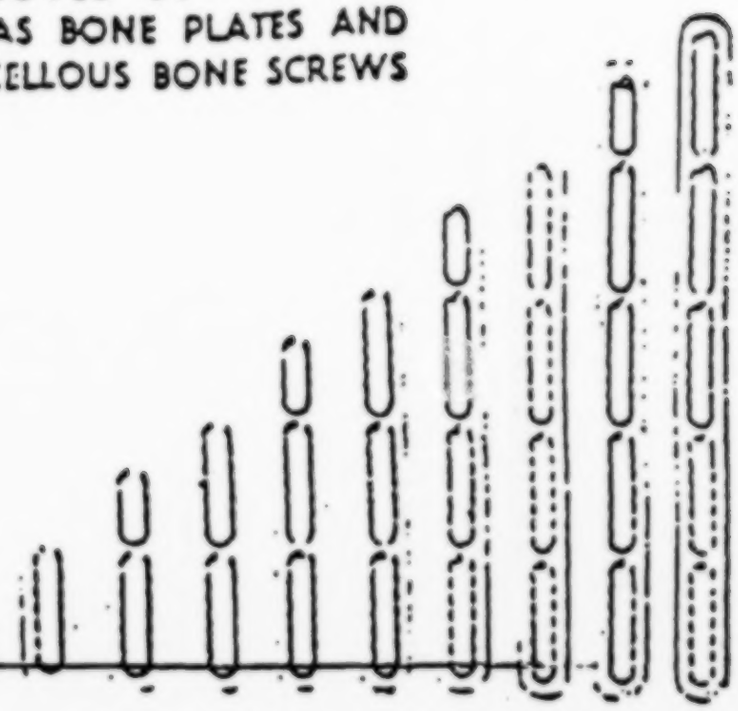
Recommended Basic VSP Instrument Set consists of: 2025-40, -41, -4100, -42, -70, -72, -74, -45, -46, -47, -49, -52 and -54

FOR INVESTIGATIONAL USE

VSP SPINE PLATES

Segmental spine plate system for internal fixation of the unstable lower thoracic and lumbar-sacral adult spine at single and multiple segmental levels. Transpedicular Screws (2026-22 through -34) placed bilaterally through the pedicles and into the vertebral bodies and stabilized with VSP Spine Plates secured by specially designed Nuts provide immediate, strong and rigid fixation. Available in 1 through 5 slots in half slot increments. Longer plates available on special orders.

APPROVED BY FDA FOR USE AS BONE PLATES AND CANCELLOUS BONE SCREWS



01° 1.5° 2° 2.5° 3° 3.5° 4° 4.5 5.

Order No.	Description † Length	Width
2025-01	1.75 in. (44mm)	.62 in. (16mm)
2025-1.5	2.70 in. (68mm)	.62 in. (16mm)
2025-02	3.25 in. (84mm)	.62 in. (16mm)
2025-2.5	4.20 in. (106mm)	.62 in. (16mm)
2025-03	4.75 in. (120mm)	.62 in. (16mm)
2025-3.5	5.70 in. (144mm)	.62 in. (16mm)
2025-04	6.25 in. (158mm)	.62 in. (16mm)
2025-4.5	7.20 in. (182mm)	.62 in. (16mm)
2025-05	7.75 in. (196mm)	.62 in. (16mm)

U.S. and foreign patents pending
* Recommended for initial order
† VSP Plates are manufactured of certified implant grade Stainless Steel

[Exhibit I to Declaration of Carl A. Larson, Ph.D. omitted]

Exhibit J to Declaration of Carl A. Larson, Ph.D.
[See following inserted pages]

[Remaining Exhibits to Declaration of Carl A. Larson, Ph.D., omitted]

Spine Plat
Patier
Informatio

Sanford H. Davne, M.D.
Donald I. Myers, M.D.

1015 Chestnut Street
Mezzanine
Jefferson Building
Philadelphia, PA 19107

BEST AVAILABLE COPY

Low back pain, with or without accompanying leg pain, is the result of a number of causes, either separately, or in combination.

1. Your pain may be due to the pressure of soft tissue, such as ligaments or bone on a spinal nerve. This pressure irritates the nerves that, in turn, causes back and/or leg pain.

2. Another major cause of pain occurs when one vertebra rubs against another vertebra when you move your back. The pain that is produced in this way may decrease or go away entirely if you immobilize your spine. Unfortunately, the only way that you can do this, without surgery, is to stay in bed, flat on your back. In that respect, bed rest is a solution, but who wants to live the rest of their life flat on their back?

3. Previous unsuccessful spine surgery can also be a cause of continuing back and leg pain.

4. Accidents, either at home or on the job, that cause trauma to your back, such as fractures, can cause back and leg pain.

5. Tumors, originating in the spine, or from elsewhere in your body, can cause pressure in your spine and result in back and leg pain.

6. All sorts of misalignments of your spine, either vertically, or from side-to-side, can give you pain in your back or legs.

All of these causes of pain are either directly or indirectly related to the relative stability and proper alignment of your spine.

Your doctor, after a careful and thorough physical examination that includes reviewing the results of sophisticated tests and x-ray procedures will be able to diagnose your condition and recommend a course of treatment that should relieve your symptoms.

TREATING LOW BACK PAIN

In order to correct your spinal instability and/or alignment problems, your surgeon has chosen an operation that includes fusion of your vertebra, nerve root decompression, and fixation using spine plates.

Spinal fusion is designed to stop all motion between any two vertebra in your back. This is done by inserting blocks of bone (either your own bone, taken from your hip, or bone obtained from a bone bank) into the space between the vertebra. These bone blocks, or grafts, eventually grow together, or fuse, and in doing so entirely eliminate the movement of this section of the spine and remove one of the initial causes of back and leg pain. (Fig. 3)

You can reasonably expect these bones to fuse into a solid mass in about six months.

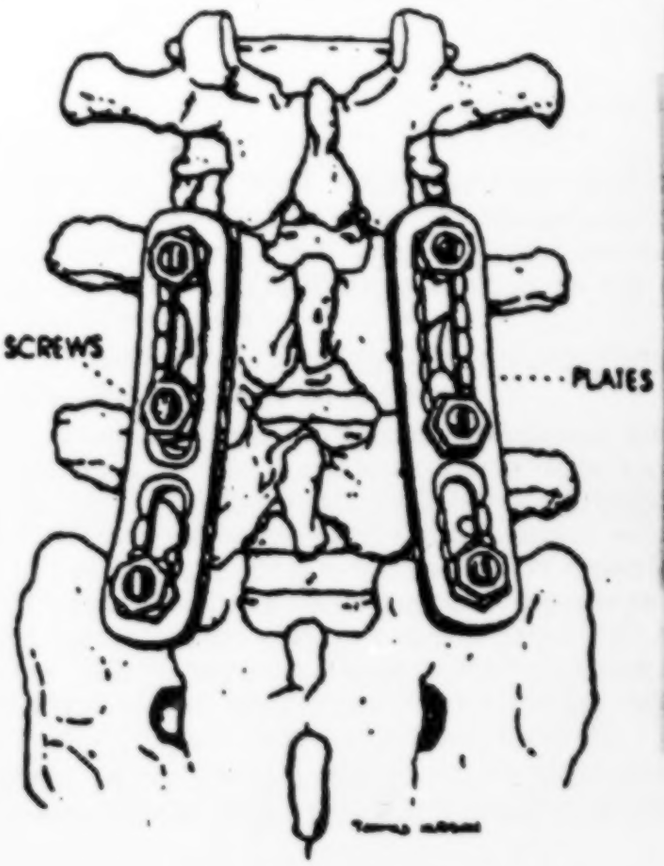


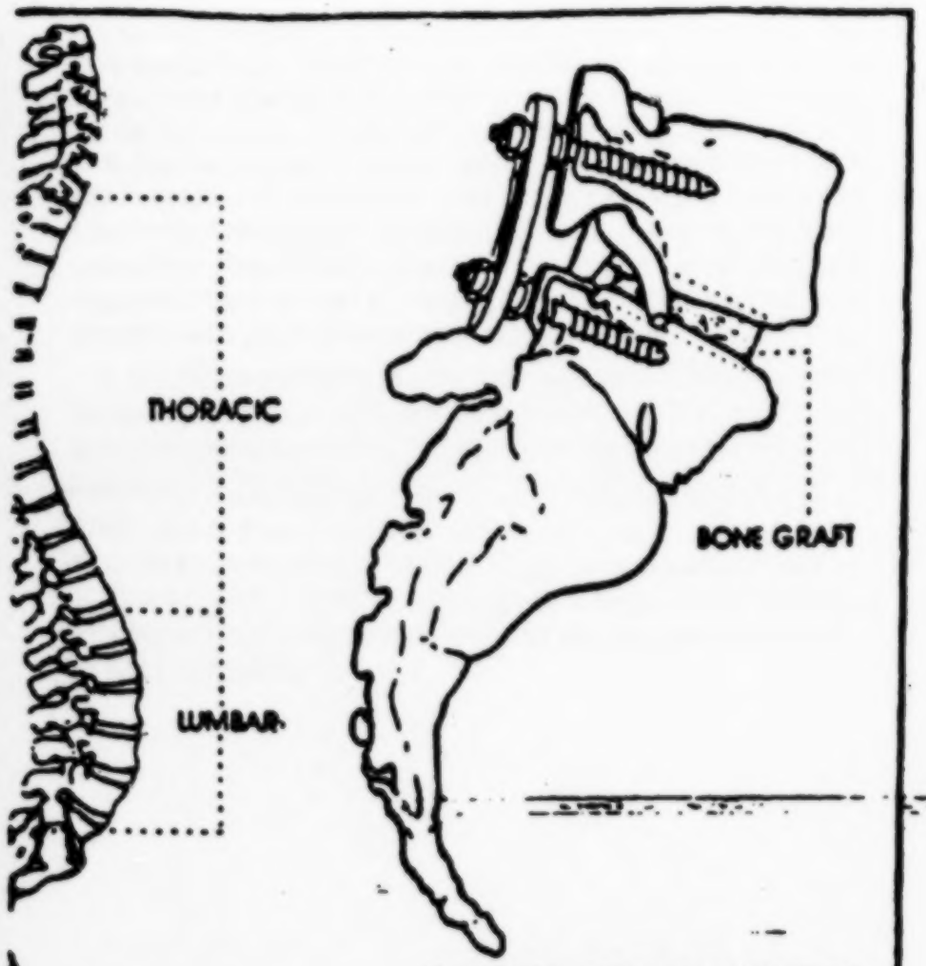
Fig. 1 Spine plates and screws in place

A nerve root decompression is achieved when your surgeon removes some or all of the bony structure and soft tissue that covers the top of your spinal column, thereby freeing or "decompressing" the nerve roots that branch out from your spinal cord. When this pressure is gone, another cause of back and leg pain is alleviated.

Finally, in order to insure that all this work will give you lasting relief from back and leg pain, your surgeon completes the operation by using spine plates to stabilize your back in the best possible position. Achieving spinal fusion in an unstable or misaligned spine without spine plates is very difficult because there is nothing to prevent your spine from moving while the bone between your vertebra is fusing.

Studies have shown that fusion progresses best when the spine is rigid and the bone grafts are kept compressed under constant pressure. In order to decrease motion in your spine and in order to add rigidity to your spine after extensive nerve root decompression, spine plate surgery was developed.

Spine plates consist of two stainless steel plates with nested slots for the insertion of screws. (Fig. 1) At the right time during your surgery, screws and spine plates are inserted and joined together on each side of the vertebral spine, and adjusted to bring the vertebra into firm alignment. Once this has been achieved, all of the elements that your surgeon has brought together work to give your spine a better shape, and prevent movement of the vertebra, thereby eliminating another cause of pain.



2 Spinal column

Fig. 3 Plates and screws attached above and below

Your surgeon has determined that your particular problem originates in the spinal column at one or more vertebral levels in the thoracic or lumbar spine (Fig. 2) and will be able to indicate the probable problem area to you on a model or drawing. It is important for you to understand that a back problem may exist at one or more of these levels. When spine plates are used in conjunction with a spinal fusion and nerve root decompression, the plates are usually applied to one vertebral level above and to one vertebral level below the affected area, in order to insure adequate fixation while the vertebra are fusing. (Fig. 3)

As is the case with surgery of this magnitude, a moderate amount of blood is lost during this procedure. To replenish this loss, blood transfusions are commonly administered during surgery. Typically, this operation will take from 2 to 4 hours, depending on the number of levels involved, and the extent to which the spine needs to be realigned or repaired.

POST-OPERATIVE EXPECTATIONS

Length of Hospitalization: On the average, 10 or 14 days. However, since your recovery rate will vary according to such factors as age, weight, fitness level and general health, the actual length of your hospital stay will be determined in consultation with your surgeon. You will probably be up and walking 1 to 3 days following your surgery.

You will experience some fatigue and post-operative pain, but as you regain your strength, and begin caring for yourself the fatigue and pain will diminish and eventually disappear as you gradually resume your normal pre-operative activity level.

All forms of lifting and carrying are to be avoided until otherwise indicated by your surgeon.

You may wonder if you will be able to bend over following spine plate surgery. The answer is, "Yes!" Functionally, spine plates do not hinder your motion. You will probably regain full or almost full range of motion.

POSSIBLE COMPLICATIONS

Any surgery, no matter how minor or major, carries with it possible complications. The following list of complications is included for you to discuss with your surgeon so that you will be able to make the best decision possible in your case. If you have any other concerns, please feel free to speak frankly with your doctor before agreeing to undergo surgery. Sharing your concerns, and resolving reasonable doubts that you have will contribute to your peace of mind, and will ultimately allow you to chart the best course of action.

1. **Infection.** This is a serious complication. To decrease the likelihood of infection, antibiotics are administered as a preventive measure. If you are allergic to specific antibiotics, remember to tell your doctor before surgery. There are many alternatives available. In the event that an infection does occur, prompt treatment will resolve the problem quickly and with a minimum of discomfort and risk. Sound post-operative care and observation by hospital staff will minimize the chance that an infection will develop. Follow your doctor's directions faithfully and infection should not be a problem.

2. **Screw Breakage.** If a screw becomes loose or breaks, it may need to be surgically replaced and/or removed. Your implants are not intended to replace normal body structures, or bear the weight of the body in the presence of incomplete bone healing or fusion. A delayed fusion or non-union of bone, which may occur for reasons beyond the control of the surgeon, will result in excessive and repeated stresses that are transmitted by the body to the screw.

Due to normal metal fatigue, excessive and repeated stress can cause eventual bending and/or breakage of screws. A bent or broken screw, however, does not necessarily determine the success or failure of the procedure. As the bone heals, the plates and screws are no longer functional, although they remain in place permanently.

3. **Bursitis.** Sometimes a small protective pocket of tissue, or bursa, develops over an irritated or surgically altered

area. The swelling that occurs may cause tenderness, and the bursa may need to be evaluated. In some cases the screw that seems to be causing the tenderness may have to be removed. In other cases, the swelling subsides and the problem goes away. In either case, consultation with your doctor is indicated, and an appropriate course of treatment should be decided upon. In many cases, conservative treatment, that is, taking a wait-and-see approach, is the best choice. In all cases, you need to work closely with your physician to decide what is best for you.

4. Continued Pain. Usually, pain associated with surgery recedes with time. On rare occasions, you may find that the pain continues. If this happens to you over an extended period, inform your doctor of your lack of progress, and work together to determine if further evaluation is indicated.

5. Dural Leak. The outer membrane covering the spinal cord is called the DURA MATER. Sometimes during surgery, or more infrequently, during pre-operative studies, this membrane is punctured. If this happens, spinal fluid leaks or seeps into the surrounding tissues. This leakage is readily detected by your physician, and if the puncture does not heal, further surgery is sometimes needed to repair the leak. Your surgeon will be able to discuss the indications for this complication with you and describe what is done in this situation.

6. Non-Union. This complication results when the bone fails to fuse, or join. During the operation your surgeon inserts a bone graft to stabilize your spine. Usually, the graft fuses and becomes solid. Sometimes, however, for reasons that are not fully understood, the bone graft does not fuse. This non-fusion or non-union may subsequently cause some discomfort. Non-fusion can be detected in post-operative x-rays, and may be the cause of some discomfort. If subsequent x-rays fail to show progress toward fusion and your discomfort continues, the first grafts may have to be removed and replaced with new grafts. As noted above, a non-union may also result in screw breakage. Replacing the bone graft usually resolves this complication. Again, your surgeon is best equipped to discuss this complication with you, and to chart an appropriate course of action.

CONCLUSION

Although each patient is unique, you should notice a marked improvement in your condition after spine plate surgery. Most patients achieve results, and are eventually free of pain and better able to participate in all or most of their desired normal daily activities. Now that you have had a chance to read and think about spine plate surgery, you should take the time to carefully weigh the pros and cons presented in this pamphlet and discuss your situation with your surgeon.

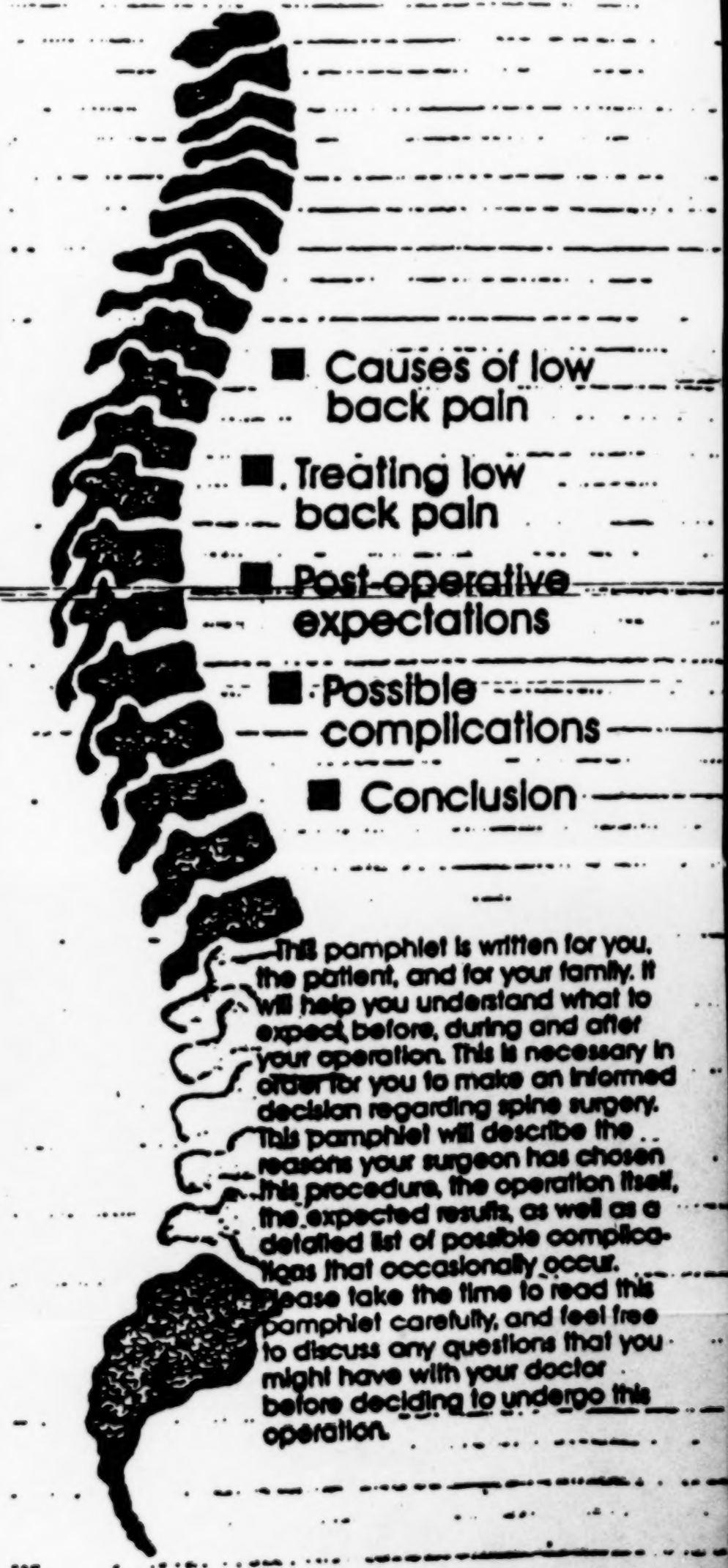


EXHIBIT 9

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: ORTHOPEDIC BONE SCREW PRODUCTS LIABILITY LITIGATION	MDL DOCKET NO. 1014

THE DEPOSITION OF PAMELA BUCKMAN
MARCH 20, 1996

*** [154] *** Q. It was the FDA's position that your submission did not demonstrate that any manufacturer had produced and labeled a product for pedicle placement that would qualify as a predicate device?

A. That's right.

Q. You say that, "FDA made it to clear to

[160] us that the VSP system must be handled through the IDE/PMAA mechanism for spine indications." That was consistent with your recollection of that meeting?

A. That's right.

Q. Who specifically at the FDA made that clear?

A. It would have been Dan or Tom, Dan McGunagle or Tom Callahan.

Q. You say, "They also made it clear that they would consider the VSP plate and the VSP screw as a bone plate and cancellous bone screw respectively. Dan McGunagle made a comment to the effect that we would be required to satisfy the requirements for a 510(k) for each product but that they promised to review these documents promptly."

Whose idea was it to consider the VSP plate and VSP screw as a bone plate and bone screw?

A. Dan McGunagle's.

Q. Had anyone from AcroMed brought up that suggestion in the meeting?

A. No.
[156] Q. At what point in the meeting did that suggestion come up?
A. I don't remember.
Q. Do you remember — as specifically as you can, can you tell me what was said about that?
A. Dan suggested that the plate and the screw would be reviewed as a bone plate and a bone screw if in fact we could produce a document that allowed them to find a substantially equivalent rendering or decision based on what we submitted.
Q. In that meeting, to your recollection, did anyone tell anybody at the FDA that the VSP plate or the VSP screw had clinical applications other than in the spine?
A. Dr. Steffee.
Q. And specifically what did Dr. Steffee tell the FDA about the plate and screw?
A. I specifically asked Dr. Steffee toward the conclusion of the meeting if that bone plate and bone screw could be used anywhere other than the spine, and he clearly said, "Yes, I've done it."
* * * [160] * * * Q. Was there any discussion about safety and effectiveness concerns with the VSP plate and screw if it was to be sold as a bone plate and bone screw?
A. No.
Q. To your understanding, did the FDA as of this meeting — as of the conclusion of this meeting in December of 1985 still pose those same safety and effectiveness concerns that we discussed earlier relating to this device?
A. For its use in the spine?
Q. Yes.
A. Yes. * * *
[420] * * * Q. Ms. Buckman, as early as 1985, am I correct that the FDA had communicated to you in words or substance that they had concerns about the safety and effectiveness of pedicle screws?
A. Yes.

Q. Those same concerns you communicated to AcroMed. Is that correct?
A. Yes. * * * *

EXHIBIT 10

December 21, 1985

Edward Wagner
AeroMed Corporation
2450 Prospect Avenue
Cleveland, OH. 44115

Dear Ed,

So that we may understand where we are and where we are going, I thought it wise to commit a few issues to writing.

Report of Meeting with FDA December 12, 1985, Present for FDA were Ed March, Tom Callahan, Dan McGungle and Ken McDermott. Present for AcroMed were yourself, Dr. Steffe, Dr. Graves, Mr. Radzius and myself.

After some discussion, it was apparent that FDA will not accept the 510K as means for reviewing the clinical data for the VSP plate in the "spine" location. On the other hand, they readily agreed that bone plates and bone screws — labeled as such — are "510K able".

Labeling which specifies or implies use of the plate or screws in the spine can only be reviewed via the PMAA process. Dan McGunagle told as we could go to a PMAA on the data we have with the 153 patients. An IDE is only necessary if we wish to add to the number of patients in the study group. The orthopaedic panel typically relies on 100 or more patients with a minimum two year follow up period.

To increase our chances of approval of the PMAA we will need to update the data on the original 153 patients to capture the longer follow up. Additionally, I feel we should gather data from one more

center. Dr. Steffee suggested Seattle. In my experience, three centers is usually the minimum the panel likes to see.

We discussed the pros and cons of filing an IDE for the spine indications. I think we all agree that the patients studied thus far have all been Dr. Steffee's patients and/or under his very close supervision and direction. If you wish to add investigators and display the device at AAOS, we must have an IDE.

Timing is obviously very important here as the AAOS opens February 20, 1986. This is how I suggest we proceed.

1. File a 510K for the bone plate immediately.
2. File a 510K for the bone screws imediately.
3. File an IDE for spine indications for the plate/screw system. This should be accomplished as early in January 86 as possible.

We probably won't get approval on all this by AAOS time. However, we will be on the right track and I believe FDA will work with us to develop appropriate language etc. for use at the AAOS.

Please look at the instruments that you want to show. Are there any that we have not filed on a 510K?

Please have Dr. Steffee send us the information we discussed right away. This includes articles on screws without hex heads, the IRB approval letter from St. Vincents, the informed consent form you have used in the past, the name and address of the surgeon in Seattle and anything else you can think of!

In the meantime you should review the labeling on the bone plates and screws. There should be no language which suggests the indications for use of the plates and screws other than in "bone". Which bone is up to the surgeon to decide.

We will continue to work on the package inserts for you. Our first priority will be something to go into the IDE as proposed labeling for the spinal indications.

Also for the IDE, we will design a data collection form for use with our established data management and analysis programs. Much of this has been initiated already for the data collected to date. Dr. Steffee indicated that Lynn Topham is working on some kind of program along these lines. Please remind Dr. Steffee to have Lynn call us. We will begin discussions here with Dr. Carlov our computer specialist.

In regard to your letter to Mr. Eckart, it is thorough and well written. The arguments you make have been stated before and continue to be areas of concern. I personally question whether or not anything is to be gained by sending the letter. On the other hand, I'm not sure anything will be lost either. The only risk I see is the possibility of offending a reviewer at FDA or a panel member. Frankly, I don't think this is very likely. Certainly the decision is up to you. Perhaps Joe Radzius would have more to say on this topic.

Speaking of Joe, he mentioned that he would draft a letter to attempt withdrawal of all information previously submitted on the VSP under a 510K. For competitive reasons, I think this would be wise. Perhaps you should remind him. If he does not have the time, I can write this letter for you. Please let me know what you and Joe decide.

Well, this should keep us busy for a day or so at least! It was good to see you. I look forward to meeting with you and Dr. Steffee in New Orleans. By the way, I have rooms blocked at the International Hotel. Do you need any? See you soon.

Sincerely,

/s/

Pamela M. Buckman

cc: Joseph Radzius, Esq.

[Exhibits 11-41 omitted]

EXHIBIT 42

Department of Health & Human Services
Public Health Service
Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

Oct. 7, 1991

Mr. William Christianson
Regulatory Affairs
AcroMed Corporation
3303 Carnegie Avenue
Cleveland, Ohio 44115

[Received: Oct. 10, 1991, AcroMed Corporation, Cleveland, Ohio]

Dear Mr. Christianson:

We have received your letter of July 5, 1991, and the two-page package insert entitled, "VSP Bone Plates and Bone Screws," which was provided for our information. The comments set out below reflect positions that undoubtedly have been known to your company for years.

The information we have indicates that AcroMed has promoted, advertised, represented, and commercially distributed VSP Bone Plates and Bone Screws for use in the spine, and that this was the intended use for these devices from the start. As you know, VSP

Bone Plates and Bone Screws are Class III medical devices when intended for use in the spine, and, therefore, should have had an approved premarket approval application (PMA) for this use. Since AcroMed has never had such approval, it has never had any legal right to label (or advertise, promote, represent, or commercially distribute) VSP Bone Plates and Bone Screws for use in the spine. AcroMed received FDA approval of an Investigational Device Exemption (IDE) application (G860013), which permitted limited distribution of the VSP Bone Plate and Bone Screw for use in the spine as part of a controlled clinical investigation, subject to the requirements of 21 CFR Part 812; however, this IDE was withdrawn in our letter dated April 26, 1990.

To date, FDA has not approved AcroMed's PMA application for the Variable Screw Placement (VSP) Spinal Fixation System (P900040). As you know, without such approval, AcroMed cannot lawfully label, advertise, promote represent, or commercially distribute VSP Bone Plates and Bone Screws for use in the spine. Any direct or indirect references to the use of VSP Bone Plates and Bone Screws for spinal fixation, including any references to investigational use, or any distribution of these devices for this intended use, except in accordance with 21 CFR Part 812, is in violation of the Federal Food, Drug, and Cosmetic Act (the Act). Moreover, any representation that these devices are approved for investigational use in the spine under 21 CFR Part 812 is also false and misleading in light of FDA's withdrawal of AcroMed's IDE. Unless and until AcroMed obtains from the FDA an approved PMA for the VSP Spinal Fixation System (P900040), labeling revisions will not prevent the VSP Bone Plate and Bone Screw from being adulterated and misbranded medical devices.

Sincerely yours,

/s/

William H. Damaska
Director
Division of Compliance Operations
Center for Devices and Radiological Health

cc:
Dr. Arthur D. Steffee
9994 Music Street
Novelty, Ohio

Jeffrey N. Gibbs, Esq.
Hyman, Phelps & McNamara, P.C.
1120 G Street, N.W.
Washington, D.C. 20005

[Exhibit 43 omitted]

EXHIBIT 44
MEMO OF MEETING

BETWEEN: Jeff Gibbs, Jim Phelps — Hyman, Phelps and McNamara

Mr. Christianson, Ms. Lanlatz — Acromed Corporation

AND

Ron Johnson-CDRH, Dr. Nirmal Mishra-CDRH, Karen Stutzman-CDRH, Edie Snyder-MIN-DO, Larry Spears-CDRH, Charles W. Sedgwick-CIN-DO, Mr. Steve Keller-DOJ

DATE: March 7, 1994

In a meeting arranged by the Director of Compliance for CDRH, Ron Johnson, Messrs. Jeff Gibson and Jim Phelps of the law firm Hyman, Phelps, and McNamara, and Mr. Christianson and Ms. Lanlatz of the Acromed Corporation met to discuss the Corporation and their potential prosecution.

The subject of the meeting generally followed the format of the attached 12-1-93 letter to the Center. The counsel for the firm, Mr. Gibbs, emphasized the need to have the industry and the FDA cooperate and that prosecution would be an impediment to this cooperation. Specifically, the cooperative efforts involved an industry-funded study (17 firms) which was reviewing the pedical screw issue. Mr. Christianson advised that because of the time interval involved in the study (1990 and 1991), most data collected would come from Acromed. The counsel advised that an indictment of Acromed would cause firms to be less willing to cooperate with the study.

A second issue for Acromed is the industry's (Acromed) view that the Center is sending mixed signals to the industry by "approving systems" for non-pedical use when the known use (supposedly to the center) is for the pedical.

A third area visited was the issue of responsibility. Mr. Christianson advised that the corporate management had changed, i.e. Mr. Ed Wagner was retired (or resigned?) and that the Board of Directors had been expanded to include two "outside" members. Ms. Lanlutz acknowledged that both William and Arthur Steffee were still board members.

The fourth issue concerned "confusion in guidance" on how products should be labelled, i.e: requiring the statement on pedical screws etc., (i.e. "not for pedical use" and then requiring the removal of the same).

Emphasis was placed upon FDA being unable to "keep up with technology" and suggesting that the FDA's failure to approve the VSP system and pedical screw was no reason for an innovative and competent firm to not market the state of the art technology.

Acromed's counsel highlighted that any legal action on the government's part would foster additional private suits. We were advised that there were currently 6 or 7 class action lawsuits pending against Acromed. The current "20/20" program acknowledging a grand jury investigation has had an adverse effect on the firm. Mr. Christianson advised that the firm has paid an estimated $700,000.00 to date responding to subpoenas, etc.

The firm's letter and presentation was a plea to drop any further grand jury/prosecution action based upon the mixed signals received by the firm and the unfairness implied by the prosecution proposal. The representative asserted several times that other firms were marketing not only pedical systems but other medical devices for purposes for which they were not approved [i.e. 510 (k)] and that although FDA was aware of such practices, only Acromed was the subject of a potential prosecution. The firm's counsel advised that after two years, the firm had not as yet received a copy of "the 85 document" on the meeting the firm had with members of the CDER staff.

cc: Brunswick R.P.
Leonard J. Farr
Karen Stutzman

[Remaining exhibits omitted]

IN THE UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF PENNSYLVANIA

[Caption omitted]

Buckman Company's Reply Memorandum
In Support Of Motion to Dismiss Omni Complaint
For Failure To State A Claim Upon Which Relief
May Be Granted

Filed January 31, 1997

[Text of Reply Memorandum omitted]

EXHIBIT 1

Jones, Day, Reavis & Pogue
North Point
901 Lakeside Avenue
Cleveland, OH 44114

* * * March 1, 1996

Edward J. Parr, Jr., Esq.
Office of General Counsel
United States Food and Drug Administration
Department of Health and Human Services
Rockville, Maryland 20857

Re: Orthopedic Bone Screw Litigation

Dear Mr. Parr:

The Food and Drug Administration is familiar with the pending litigation involving orthopedic bone screws. You and other counsel

for the FDA have attended depositions in these cases, and the FDA has obtained the right to review the discovery record generated in the federal MDL proceeding. The FDA is therefore now presumably aware that plaintiffs have alleged that AcroMed Corporation defrauded the FDA during a meeting between AcroMed and FDA officials that occurred on December 12, 1985. Those allegations are unfounded; indeed, they are belied by a memorandum written by an FDA official. I have enclosed a copy of that memorandum for your information.

In light of the allegations made by plaintiffs, and their potential impact on this litigation, AcroMed Corporation would like to take very limited depositions on written questions, pursuant to Federal Rule of Civil Procedure 31, of Thomas Callahan and Daniel McGunagle, two FDA employees who attended the meeting on December 12, 1985. We believe that these limited depositions are essential to allow us to demonstrate that plaintiffs' allegations of fraud on the FDA are false. The limited depositions that we contemplate will not invade any deliberative process of the FDA or unduly interfere with the conduct of the Agency's business.

Please consider this letter as a request for testimony on behalf of AcroMed Corporation pursuant to applicable FDA regulations, including 21 C.F.R. § 20.1. To assist you and the questions that we propose to use to take the depositions under Rule 31.

I look forward to hearing from you on this matter. Thank you for your assistance.

Very truly yours,

/s/
Richard I. Werder, Jr,

Enclosures
bcc: Stephen S. Phillips, Esq.

What is your name?

By whom are you employed?

For how long have you been employed by the FDA?

What is your position with the FDA?

For how long have you held that position?

What was your position at the FDA as of December 12, 1985?

Did you attend a meeting between representatives of AcroMed Corporation and FDA officials on December 12, 1985?

Who was present during that meeting on behalf of FDA?

Who was present during that meeting on behalf of AcroMed?

Describe in as much detail as you can remember the conversation that took place during the December 12, 1985 meeting.

During the December 12, 1985 meeting, did the AcroMed representatives demonstrate to the FDA the use of plates and screws in a model of the human spine?

During the December 12, 1985 meeting, did FDA officials tell AcroMed that FDA would not clear AcroMed's plates and screws for marketing if they were labeled as a "spine plate fixation system"?

During the December 12, 1985 meeting, did FDA officials tell AcroMed that because of the similarities between AcroMed's plates and screws to ordinary bone plates and screws, AcroMed's plates and screws could be cleared for marketing when labeled as simple bone plates and bone screws?

During the December 12, 1985 meeting, did Daniel McGunagle advise AcroMed's representatives that Dr. Arthur Steffee could publish papers in the peer-reviewed journals describing his findings

from the use of plates and screws for spinal fixation without violating the Food, Drug and Cosmetic Act?

During the December 12, 1985 meeting, did Daniel McGunagle advise AcroMed's representatives that Dr, Arthur Steffee could publish papers in the scientific literature describing his findings from the use of plates and screws for spinal fixation without violating the Food, Drug and Cosmetic Act?

During the December 12, 1985 meeting, did Daniel McGunagle advise AcroMed that Dr. Steffee could make scientific presentations at professional society meetings describing his findings from the use of plates and screws for spinal fixation without violating the Food, Drug and Cosmetic Act?

During the December 12, 1985 meeting, did FDA officials discuss with AcroMed FDA's policy of not regulating the practice of medicine by individual physicians?

During the December 12, 1985 meeting, did an FDA official indicate that if individual physicians chose to use plates and screws for spinal fixation, that usage would fall under the practice of medicine exception and would be outside of FDA's authority?

During the December 12, 1985 meeting, did AcroMed explain to the FDA that it would be submitting two new 510(k) submissions, one for the plates labeled as simple bone plates and one for the screws labeled as simple bone screws?

Does the attached memorandum from Chief, Orthopedic Devices Section, to Karen Stutsman and others, dated April 5, 1990, accurately describe the meeting held between AcroMed and the FDA on December 12, 1985?

Who wrote the memorandum from Chief, Orthopedic Devices Section, to Karen Stutsman and others, dated April 5, 1990?

If you wrote the April 5, 1990 memorandum, did you do so in the regular course of your duties at the FDA?

If you wrote the April 5, 1990 memorandum, when you did so did you know that other FDA employees would rely on the accuracy of the memorandum during their official duties?

Did you write the handwritten sentence that follows the third paragraph on page one of the' April 5, 1990 memorandum?

What does that handwritten sentence say?

Do your initials appear in the margin next to the handwritten sentence?

The April 5, 1990, memorandum indicates that it was sent "to" Karen Stutsman and Leonard Farr "through" Thomas J. Callahan and Carl A. Larson. What does it mean to send a memorandum "through" Carl A. Larson?

Did you send the April 5, 1990 memorandum "through" Carl A. Larson?

Did you send a copy of the April 5. 1990, memorandum to Carl A. Larson?

Did Carl A. Larson ever send you a written response to the April 5, 1990 memorandum?

What, if anything, did Carl A, Larson say in that written response?

Did you ever receive any oral response from Carl A. Larson to the April 5, 1990, memorandum?

What, if anything, did Carl A, Larson say in his oral response to the April 5, 1990 memorandum?

Did Carl A, Larson ever tell you, orally or in writing, that any statement contained in the April 5, 1990 memorandum was inaccurate?

Did AcroMed submit a 510(k) notification for an "AcroMed Nested Bone Plate" (K855224) that was dated January 10, 1986 and received by the FDA on January 17, 1986?

Did you participate in the review process for AcroMed's 510(k) notification for its "Nested Bone Plate"?

When you were participating in the review of AcroMed's 510(k) submission for its "Nested Bone Plate," did you know that the technological characteristics of the "Nested Bone Plate" were essentially identical to the technological characteristics of the "spine plates" that had been included in AcroMed's prior 510(k) notification for a "Variable Screw Placement (VSP) Spinal Plate Fixation System" (K853913)?

Did AcroMed submit a 510(k) notification for an "AcroMed Cancellous Bone Screw" (K860017) that was dated December 30 and 31, 1985 and received by the FDA on January 3, 1986?

Did you participate in the review process for AcroMed's 510(k) notification for its "Cancellous Bone Screw"?

When you were participating in the review of AcroMed's 510(k) submission for its "Cancellous Bone Screw," did you know that the technological characteristics of the "cancellous bone screw" were essentially identical to the technological characteristics of the "cancellous screws" that had been included in AcroMed's prior 510(k) notification for a "Variable Screw Placement (VSP) Spinal Plate Fixation System" (K853913)?

In your opinion, did AcroMed mislead you during the December 12, 1985 meeting about its intention to re-submit 510(k) notifications to obtain clearance of its plates and screws with different labeling?

MEMO

TO: Karen Stutsman, OCS, HFZ-322, Leonard Farr, CIN-DO, HFR-MA440, through Thomas J. Callahan, Branch Chief, Restorative Devices and Carl A. Larson, Div. Director, DSRD, HFZ-410

FROM: Chief, Orthopedic Devices Section, DSRD, HFZ-410

SUBJECT: December 1985 meeting between DSRD staff and representatives of Acromed, Inc., to discuss the not substantially equivalent status of the Variable Screw Placement (VSP) Spinal Fixation System.

DATE: April 5, 1990

In response to proposal for the injunction against Acromed, Inc., I have the following recollections of the December 1985 meeting Acromed Inc., now claims represents FDA sanction of their promotion and commercialization of the VSP system for spinal fixation.

In December 1985 Arthur Steffee, M.D., Edward Wagner, Joseph Radzius, Pam Buckman and 2 other gentleman from Acromed, Inc., whose names escape me, met with Carl A. Larson, Thomas Callahan, and myself. The Acromed, Inc., representatives had come to protest the not substantially equivalent decision that had been given in response to K853913.

The post-Amendments status of transpedicular screw spinal fixation systems was discussed at length. Dr. Steffee was very aggravated at this and was unwilling to accept that a PMA approval was necessary prior to marketing the VSP system for spinal fixation. He and Mr. Radzius badgered the FDA staff at length demanding the right to immediately sell the VSP system for spinal fixation. [Handwritten: They said that [illegible] devices like this are already

out there (in the market) for long bone use and that their product was [illegible] these systems.]

With the meeting at a stalemate I pointed out FDA's long standing policy of evaluating (for not only substantial equivalence but safety and effectiveness) a device based on the labeling submitted for the device and the agreement between the labeling and the device's physical abilities to perform as the labeling claimed. I also pointed out that because of the physical and mechanical similarities between the plates and (the original design) screws of the system to ordinary bone plates and screws these devices, when labeled, indicated and promoted as simple bone screws and plates would, in fact, be substantially equivalent to pre-Amendments devices and could be shipped in interstate commerce. I advised Acromed's representatives that Dr. Steffee, as a publishing researcher, could publish papers in the scientific literature and peer reviewed journals and make scientific presentations before professional society meetings describing his findings from the use of the plates and screws as a system for spinal fixation without violating the FD&C Act. I pointed to the oft stated FDA policy of not regulating the practice of medicine by individual physicians. I said that if individual practitioners, on their own without guidance from labeling or promotion by the manufacturer, chose to use the plates and screws for spinal fixation that would fall under the practice of medicine and outside FDA's authority. I advised Acromed's representatives that any labeling or promotion by the firm of the VSP system for spinal fixation would be a violation of the Act and any presentations by Dr. Steffee would have to be limited to medical society meetings and professional and that these presentations would have to be limited to factual reports of the his findings and not be advertisement or promotion of the system as safe and effective for spinal fixation.

There were a few questions from various Acromed personnel as to the limitations of finding these devices substantially equivalent to

conventional bone plates and the conditions itemized above were restated by myself.

The meeting ended a few minutes later with Acromed announcing that they would be submitting a new 510(k)s, one for the plates and one for the screws.

Department of Health and Human Services
* * *

April 4, 1996

Richard I. Werder, Jr., Esq.
Jones, Day, Reavis & Pogue
North Point
901 Lakeside Avenue
Cleveland, Ohio 44114

Dear Mr. Werder:

The Food and Drug Administration ("FDA") is in receipt of your letter, dated March 1, 1996, requesting the deposition testimony upon written questions of FDA employees Thomas J. Callahan and Daniel S. McGunagle in connection with In re Orthopedic Bone Screw Product Liability Litigation, MDL No. 1014 (E.D. Pa.).

The Agency's regulations prohibit FDA employees from testifying with respect to information acquired in the discharge of their official duties except with the express authorization of the Commissioner of FDA. 21 C.F.R. § 20.1. As Director of the Office of Enforcement, I have been delegated the authority by the Commissioner to review requests for testimony pursuant to Section 20.1. For the reasons set forth below, I must deny your request.

Section 20.1 provides that a request for testimony may only be granted upon a determination that the testimony requested is in the public interest, will promote the objectives of the Federal Food, Drug, and Cosmetic Act (the "FDCA"), and will promote the objectives of FDA. However, even when these prerequisites have been satisfied, FDA has discretion to disapprove a request for testimony. Because FDA receives numerous requests for its employees to participate in litigation to which FDA is not a party, it is the policy of the Agency to decline to authorize its employees to testify in their official capacity unless there are compelling circumstances.

Compelling circumstances include cases in which an FDA employee is the only source of the factual information requested, cases in which official records are not available, or cases in which there is an overriding public health interest important enough to justify interrupting the official duties of FDA personnel. This policy has been established to protect the public health by ensuring that FDA employees spend their time pursuing their official duties and not serving as witnesses in private litigation. Our policy is also intended to avoid creating the impression that FDA or one of its employees is taking a partisan position in litigation to which the Agency is not a party.

Based upon information previously provided by your firm to the Agency in connection with the pending litigation and the record presented in your letter of March 1, 1996, there is insufficient information to satisfy the requirements of Section 20.1 or to demonstrate that compelling circumstances exist that would warrant Mr. Callahan and Mr. McGunagle taking government time to testify in the pending litigation.

Although a tremendous amount of public attention has been given to pedicle screw fixation devices, it is not in the public interest for FDA employees to stop performing their official dudes to prepare for and to provide deposition testimony for a civil action between private parties. That is particularly true in this case, in which volumes of FDA documents related to the pedicle screw have already been made available pursuant to the Freedom of Information Act ("FOIA") to both plaintiffs' and defendants' liaison counsel. These documents disclose the nature and basis of FDA action to the extent such disclosure is permitted by law.

Indeed, the written questions submitted with your letter of March 1, 1996 indicate that you already have possession of publicly available documents, such as the April 5, 1990 memorandum by Mr. McGunagle setting forth his recollections of a December 1985 meeting with AcroMed, Inc. representatives. Internal written responses to that memorandum, if any, may already have been

disclosed or may be available to you pursuant to an FOIA request. However, your written questions further suggest that you are seeking information, such as privileged agency communications regarding the December 1985 meeting, that FDA is not required by law to disclose. And, to the extent such communications involved Mr. Larson, you have already had an opportunity to pose such questions to Mr. Larson at two days of depositions taken in connection with the pending litigation.

Based on these facts, I must also conclude that Mr. Callahan and Mr. McGunagle are not the only source of the information you seek. Indeed, the proposed deponents' recollections of a meeting which took place over ten years ago is unlikely to supplement available written records. In addition, certain written questions submitted with your letter of March 1, 1996 are clearly intended to aid in the authentication of the April 5, 1990 memorandum and certain Section 510(k) notifications received by the Agency from AcroMed, Inc. Please be advised that, pursuant to 21 C.F.R. § 20.3, FDA's FOIA office will certify the authenticity of Agency records.

FDA best serves the public interest, not by providing witnesses in private litigation as you request, but rather by enforcement of the FDCA and related statutes. Even were the requested testimony and, more generally, the pedicle screw litigation, considered to serve the public interest, neither promote the principal objectives of the FDCA or the Agency. Indeed, participation by the requested Agency employees in the pending lawsuit would seriously divert those employees from their primary responsibility to review and analyze medical devices in FDA's Center for Devices and Radiological Health and to protect the public health through implementation of the various provisions of the FDCA for which they are responsible. Given the fact that FDA employees serve the public by reviewing a vast number of regulated products, permitting Mr. Callahan and Mr. McGunagle to be deposed in this case would invite requests from many similarly situated private litigants. Responding to all or

even a significant number of these requests would impede the Agency's ability to fulfill its statutory mission.

In addition, the proposed deposition testimony would not promote the objectives of the FDA. The proposed depositions would impede the Agency from implementing its plans and schedules regarding a variety of FDA regulated devices. Thus, diverting these government employees from their assigned duties can only undermine the objectives of the Agency and diminish its ability to enforce the FDCA.

The fact that your request for testimony is limited to written questions does not change my determination in this matter. FDA regards depositions, whether upon written or oral questions, as burdensome to Agency resources. For example, although your list of proposed questions is relatively short, opposing counsel would presumably be entitled to submit unlimited questions for cross-examination, which Mr. Callahan and Mr. McGunagle would be required to answer at deposition.

Accordingly, for the reasons explained above, I am unable to make any of the findings required by 21 C.F.R. § 20.1 or find compelling circumstances to justify the proposed depositions, and I must deny your request to depose Mr. Callahan and Mr. McGunagle. If you have any questions regarding this matter, however, please contact Edward J. Parr, Jr. in FDA's Office of the Chief Counsel, at (301) 827-1143.

Sincerely yours,

/s/
Daniel L. Michels
Director
Office of Enforcement

IN THE UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF PENNSYLVANIA

[Caption omitted]

Transcript of 2/6/97 Hearing Before Judge Bechtle

[178] * * *

THE COURT: Who was deceived?

MR. FISHBEIN: The government was deceived, your Honor.

THE COURT: Tell me how.

MR. FISHBEIN: The government was deceived because — let's take Buckman as an example. Well,

[179] let me back up factually.

Buckman in 1994, originally presented the FDA with a 510(k) notification and said, we want clearance to market the VSP spinal fixation system as a spinal system. It is a spinal system. The FDA said, no, no, you can't have that. It is not substantially equivalent. We have questions about the safety and the efficacy, you can't do it.

So Buckman turns around about a year later, and they change the — they cross off the name in the application, they change it to nested bone plates and cancellous bone screws, they present it to the FDA. They say, okay, FDA take a look at this 510(k) notification. This is for bone plates and bone screws to be used in the long bones of the arms and legs. Will you clear it?

Now the FDA maybe efficient in some respects, maybe not, I think we just saw this notification about a year ago or less than that.

THE COURT: At this point, they were not deceived.

MR. FISHBEIN: Right. They wrote to Buckman. In fact, they said, Buckman, would you please tell us what is going on here? What do you intend to use this product for? Buckman writes back

[180] in a letter of January 10, 1986.

The proposed indications for use of the AcroMed device are the same general indications proposed for the AO system of plates, more specifically for purpose of this 510(k), the AcroMed plates are intended for use in appropriate fractures of long bones of both the upper and the lower extremity, and such other flat bones as in the fractured pelvis that may from time to time require stabilization with contourable, metallic, non-compressing plates. They said this is a long bone fixation device. This is how we intend to use it. This is the kind of device that you should approve, FDA. The FDA, based on that representation, said, we know they are not appropriate as a spine device.

THE COURT: What?

MR. FISHBEIN: You have 510 (k) clearance to market this device.

THE COURT: For what?

MR. FISHBEIN: They say for the proposed indications. Long bone.

THE COURT: FDA was not deceived.

MR. FISHBEIN: In my view, your Honor, the FDA was deceived because here is, I think, the

[181] central point, unlike other devices that have multiple indications and can be used in multiple ways, the VSP device didn't. It wasn't a long bone use. It wasn't a long bone — I'm sorry. It was not a long bone fixation device. It couldn't be used as a long bone fixation device, AcroMed didn't intend it that way, Buckman didn't intend it that way. Nobody intended it that way. It was never used that way. It couldn't be used that way and it was just a lie so they could get this clearance then proceed with the second part of their plan, which was to go out in the market and get doctors to say, you can use it for, in our own medical judgment, we think you can use it as a spinal fixation device. In fact, our discovery revealed it was never used.

[182] THE COURT: How was the FDA compromised?

MR. FISHBEIN: The FDA was compromised.

THE COURT: They didn't believe Buckman.

MR. FISHBEIN: When they got the second —

THE COURT: It mean it would seem to me it's likely they were not fooled by Buckman because they said you offered it for this, you can use it for this. They may have said in their private quarters, "We think this spinal key really wants to use the long bone thing for the spine. We believe it's appropriate for long bone and we'll limit it to that."

Tell me about the fraud.

MR. FISHBEIN: The fraud, your Honor, is that that was not a truthful statement. If Buckman had made a truthful statement, the FDA would never have issued the clearance and the device could not have been placed in distribution.

THE COURT: Who said they never would have issued for long bone? Who said the FDA, if they had known that doctors might use this for pedicle that they would not issue it for long bone.

MR. FISHBEIN: The question is not the limitation for long bone. The question is, the FDA depends on truthful representations and because Buckman said long bone, the FDA granted the clearance which was the legal ticket in the marketplace.

Our position is, if Buckman had told them the truth, [183] the truth being that this device is not intended for long bone use, then the FDA as evidenced by their prior conduct could not legally have cleared it. It would never have had a legal ticket into the marketplace and all of the subsequent promotional shenanigans could not have taken place.

THE COURT: All right, let's assume for the moment that FDA was misled and they approved it for the described uses in the application, which was not spinal fixation.

MR. FISHBEIN: Correct.

THE COURT: So they went out into the market place and promoted it for spinal fixation.

MR. FISHBEIN: Correct.

THE COURT: What does that have to do with anything FDA did?

MR. FISHBEIN: Because —

THE COURT: How did that program make any difference? What if FDA said, "We won't approve this for long bone"?

MR. FISHBEIN: Then the device would not have come into the market. The FDA is the gatekeeper. The product — if it does not have a 510(k) clearance, it's subject to seizure. It can't be placed in commerce for any purpose, at all.

So this became the legal ticket by which it was placed into the marketplace and it's the but for the reason why the [184] product got into the marketplace, which was a scheme hatched between Buckman and AcroMed to promote it for a so-called "off label use." * * * *

9-13, 2000 (9)

No. 98-1768

Supreme Court, U.S.
FILED
SEP 13 2000
CLERK

In the Supreme Court of the United States

THE BUCKMAN COMPANY,

Petitioner,

v.

PLAINTIFFS' LEGAL COMMITTEE,

Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Third Circuit

BRIEF FOR PETITIONER

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65pp

QUESTION PRESENTED

Whether federal law preempts state-law tort claims alleging fraud on the Food and Drug Administration during the regulatory process for marketing clearance applicable to certain medical devices.

RULE 29.6 STATEMENT

Pursuant to Supreme Court Rule 29.6, petitioner states that it has no parent company and that no publicly held company owns 10% or more of its stock.

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Garner v. *Teamsters Local Union No. 776*, 346 U.S. 485 (1953) 38

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Hohn v. *United States*, 524 U.S. 236 (1998) 46

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International Paper Co. v. *Ouellette*, 479 U.S. 481 (1987) 36

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Michael v. *Shiley, Inc.*, 46 F.3d 1316 (3d Cir.), cert. denied, 516 U.S. 815 (1995) 9, 10

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Miscellaneous:

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Center for Devices and Radiological Health, Food & Drug Admin., Premarket Notification Review Program, 510(k) Memorandum #86-3 (June 30, 1986) (reprinted at <http://www.fda.gov/cdrh/k863.html>) 22

Comments by Plaintiffs' Legal Committee in *In re Orthopedic Bone Screw Prods. Liab. Litig.*, FDA Dkt. No. 95N-0176 (filed March 1, 1996) 12

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FOOD & DRUG ADMIN., REPORT OF THE HALCION TASK FORCE (1996) 39

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BRIEF FOR PETITIONER

OPINIONS BELOW

The court of appeals' opinion (Pet. App. 1a-32a) is reported at 159 F.3d 817. The opinion of the district court (Pet. App. 33a-44a), which was incorporated in the order granting petitioner's motion for dismissal (Pet. App. 45a), is unreported. The original opinion of the district court (Pet. App. 46a-53a) is also unreported.

JURISDICTION

The judgment of the court of appeals was entered on November 19, 1998, and a timely petition for rehearing was denied on February 3, 1999 (Pet. App. 57a-58a). The petition for a writ of certiorari was filed on May 3, 1999, and was granted on June 29, 2000. This Court has jurisdiction under 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

The Supremacy Clause of the Constitution provides in relevant part: "[T]he Laws of the United States * * * shall be the supreme Law of the Land * * * any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. CONST. art. VI, cl. 2.

The relevant provision of the Medical Device Amendments of 1976 to the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360k(a), is reproduced at Pet. App. 59a.

STATEMENT

This case raises important questions concerning the preemptive scope of the Medical Device Amendments (MDA), the meaning of this Court's fractured decision in *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996), and the validity of efforts by litigants to circumvent Congress's express preemption commands through state tort claims asserting that federal administrative determinations should be

disregarded because they were the product of "fraud on the agency."

A. The Regulatory Structure Of The Medical Device Amendments

In 1976, Congress enacted the MDA, which vastly expanded the authority of the Food and Drug Administration (FDA) to regulate medical devices. At the same time that it established a comprehensive regulatory regime at the federal level, Congress sought to protect innovations in device technology from being "stifled by unnecessary restrictions." H.R. REP. NO. 94-853, at 12 (1976). Specifically, Congress attempted to shield medical devices from the "undu[e] burden[]" imposed by differing state regulation by including in the MDA a "general prohibition on non-Federal regulation." *Id.* at 45. That general prohibition, which also serves to safeguard the uniformity of the federal regulatory scheme, broadly provides that no State may impose "any requirement" relating to the safety or effectiveness of a medical device that "is different from, or in addition to, any requirement applicable * * * to the device" under federal law. 21 U.S.C. § 360k(a).

The MDA divides medical devices into three classifications based on the possible risks of harm. Devices such as tongue depressors, which present little likelihood of illness or injury, are designated as Class I and subjected only to minimal regulation, or "general controls." 21 U.S.C. § 360c(a)(1)(A). Potentially more dangerous devices, such as tampons, are designated as Class II; they face increased regulation in the form of "special controls," such as performance standards, imposed by the FDA. *Id.* § 360c(a)(1)(B). The FDA designates as Class III those devices that either (1) are "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health," or (2) "present[] a potential unreasonable risk of illness or injury." *Id.* § 360c(a)(1)(C). All post-1976 devices that are not "substantially equivalent" to a pre-1976 device initially are automatically considered Class III devices and cannot be marketed without FDA clearance or approval. *Id.* §§ 360e(a), 360c(f)(1).

Except for certain exempt devices, manufacturers must obtain permission to market post-1976 devices in one of two ways. First, for certain Class III devices, the FDA may grant approval after a thorough premarket approval (PMA) process, in which the manufacturer must present the FDA with "reasonable assurance" that the device is both safe and effective. 21 U.S.C. § 360e. Second, for all other devices, to allow competition with "grandfathered" devices that were on the market in 1976 when the MDA took effect, the FDA may permit marketing of a new device if the manufacturer submits a "premarket notification" showing that the device is "substantially equivalent" to a pre-1976 device. *Id.* §§ 360e(b)(1)(B), 360(k), 360c(f)(1)(B). The "premarket notification" route is often referred to as the "510(k)" process, after the section number in the original Act. See *Medtronic*, 518 U.S. at 478.

The FDA has established detailed requirements for manufacturers' 510(k) notifications. See 21 C.F.R. § 807.87 (1999, 1986). Manufacturers must submit "[p]roposed labels, labeling, and advertisement sufficient to describe the device, its intended use, and the directions for its use"; supporting information; comparisons with currently distributed devices; and data showing the effect on safety and effectiveness of any significant changes from the pre-1976 device. *Ibid.* Manufacturers are also required to provide "[a]ny additional information regarding the device requested by the Commissioner that is necessary * * * to make a finding as to whether or not the device is substantially equivalent to a device in commercial distribution." 21 C.F.R. § 807.87(*l*); *id.* § 807.87(h) (1986). Substantial equivalence under Section 510(k) requires that a device "ha[ve] the same intended use as the predicate device." 21 U.S.C. § 360c(i)(1)(A).

Once a device has been cleared for marketing under Section 510(k), the manufacturer may not market or promote it for uses

other than those specified in the FDA clearance. Physicians, however, remain free under federal law to employ the device for any purpose, including so-called "off-label uses." See *Ortho Pharm. Corp.* v. *Cosprophar, Inc.*, 32 F.3d 690, 692 (2d Cir. 1994). Not only has the FDA recognized the existence of off-label uses (which, as part of the practice of medicine, it cannot regulate, see 21 U.S.C. § 396), it has also stated that off-label uses "may be appropriate and rational in certain circumstances, and may, in fact reflect approaches * * * that have been extensively reported in medical literature." *Use of Unapproved Drugs for Unlabeled Indications*, 12 FDA DRUG BULL. 4, 5 (April 1982). Indeed, FDA officials have acknowledged that in certain circumstances "prescribing for off-label uses may be the very best medical practice." Nightingale, *Unlabeled Uses of Approved Drugs*, 26 DRUG INFO. J. 141, 143 (1992) (FDA Assoc. Comm'r for Health Affairs). Off-label uses of medical devices have "traditionally been regulated by the hospitals in which the physicians practice and not by the FDA." FOOD & DRUG ADMIN., UPDATE ON PEDICLE SCREWS (1993).

B. The FDA's Clearance Of AcroMed's Devices

Petitioner The Buckman Company (Buckman) is a regulatory consultant for medical device manufacturers, helping them navigate FDA procedures, plan regulatory strategy, and monitor clinical investigations. In 1984, AcroMed Corporation hired Buckman as its liaison with the FDA in an effort to obtain marketing clearance for its devices. Pet. App. 4a-5a. Buckman assisted AcroMed in obtaining clearance for the components of two orthopedic bone screw systems: (1) the Variable Screw Placement Spinal Plate Fixation System (VSP), and (2) the ISOLA Spine Fixation System (ISOLA).

1. *The VSP System.* In September 1984, Buckman, on behalf of AcroMed, submitted a 510(k) clearance notification for the VSP System. The submission stated that AcroMed intended to market the VSP as a pedicle screw for use in spinal surgery. Pet. App. 5a.

The FDA rejected Buckman's submission, finding that the VSP was a Class III device not substantially equivalent to any pre-1976 devices. A year later, AcroMed, through Buckman, submitted a second 510(k) notification for the VSP, again indicating that the device would be labeled as a pedicle screw. The FDA rejected this submission as well. *Ibid.*

In December 1985, following a meeting with FDA officials, AcroMed and Buckman separated the VSP into its component parts — the screw and the plate — and sought 510(k) clearance for each. Pet. App. 5a; J.A. 46-57. These submissions, and subsequent correspondence from Buckman, identified the devices' intended use as in the arm and leg long bones, rather than in the spine. J.A. 51, 57-58. The FDA determined that the screw and plate were each substantially similar to pre-1976 devices and cleared the products for marketing in February 1986. Pet. App. 5a; J.A. 59-62.[1]

2. *The ISOLA System.* AcroMed subsequently developed the ISOLA System, which uses screws in conjunction with rods and, in some circumstances, hooks. J.A. 17-18. In June 1988, Buckman, on behalf of AcroMed, applied to the FDA for permission to initiate clinical trials relating to use of the ISOLA in spinal applications (as it had done with the VSP, see note 1, *supra*). J.A. 18. Three months later, in September 1988, Buckman submitted three separate 510(k) notifications for the screws, rods, and hooks that made up the ISOLA System. *Ibid.* These submissions specified that the devices, like their pre-1976 equivalents, had an intended use in locations other than the pedicles of the spine. *Ibid.* In April and May 1989, the FDA determined that the rods, hooks, and screws were substantially equivalent to pre-1976 devices and cleared them for marketing. *Id.* at 19.

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[1] A month *before* the FDA granted these clearances, AcroMed applied to the agency for an investigational device exemption (IDE) in order to conduct clinical trials on spinal use of the VSP System. J.A. 63-64. The FDA granted the IDE. J.A. 12, 17-18.

In granting 510(k) clearance of the iliac screw used in the ISOLA System, the FDA informed AcroMed that the device could "not be labeled or promoted for pedicular attachment to, or fixation of, the spine." J.A. 19. The FDA also required "all labeling" of the device to "prominently state that the screws * * * are intended for sacral/iliac attachment only" as well as to include the following statement: "WARNING — THIS DEVICE HAS NOT BEEN APPROVED FOR PEDICULAR APPLICATION." *Ibid.*

Despite the limited nature of the FDA's clearances of AcroMed's devices and similar products, "[i]n practice, surgeons often use[d] orthopedic screws which FDA ha[d] cleared for other purposes * * * as pedicle screws." FOOD & DRUG ADMIN., UPDATE ON PEDICLE SCREWS. Indeed, the FDA observed in 1995 that, since at least 1992, pedicle fixation with screws has been "considered to be the standard of care by the surgical community." 60 Fed. Reg. 51946, 51947 (1995). These uses, although widespread, were all off-label, because the FDA did not clear the marketing of bone screws with a labeled indication for use in spinal surgery until January 1995. *Id.* at 51947-51948.

C. The Proceedings In The District Court

After a national television program ran a story on alleged harm caused by use of bone screws as spinal fixation devices, thousands of plaintiffs filed state-law suits against doctors, hospitals, universities, manufacturers, and regulatory consultants such as Buckman, alleging product defects and fraud in the manufacturers' representations to the FDA. The federal suits — approximately 2,300 civil cases involving 5,041 plaintiffs and 334 defendants — were consolidated in this multidistrict litigation. Pet. App. 55a.

1. *Plaintiffs' "Fraud On The FDA" Allegations.* Plaintiffs did not contend that, in applying for 510(k) clearances, Buckman or AcroMed had misrepresented any objective fact, such as the size, shape, or technical characteristics of the screws, plates, rods or hooks, or their equivalence to pre-1976 devices. Rather, plaintiffs

claimed that Buckman and AcroMed deceived the FDA as to the "intended uses" of the devices, representing that they would be labeled for long bones or other non-spinal applications while planning to market them for use in the spine. Pet. App. 6a; J.A. 15-19. In plaintiffs' view, the 510(k) clearances were the product of fraud under state law and, but for such fraud, the devices would never have come onto the market or been used in their pedicle surgeries. J.A. 21.

In addition to the statements concerning "intended use" in the 510(k) submissions, plaintiffs premised their "fraud on the FDA" claim on a follow-up letter relating to the VSP bone plates that Buckman sent in January 1986. J.A. 15-16. The letter was submitted in response to a telephone call from an FDA official indicating that there was a "need for a more definitive statement covering the intended 'indications for use' of the AcroMed Nested Bone Plate." J.A. 58. As required by the FDA's regulation (21 C.F.R. § 807.87 (1986)), Buckman provided the agency with the information requested, stating (J.A. 58):

> The proposed indications for use for the AcroMed device are the same general indications proposed for the AO system of plates. More specifically, (for purposes of this 510K), the AcroMed plates are intended for use in appropriate fractures of long bones of both the upper and lower extremity and such other flat bones (as in the fractured pelvis) that may from time to time require stabilization with contourable metallic non-compressing plates.

In their complaint, plaintiffs also cited other evidence purporting to show that Buckman and AcroMed possessed a subjective intent that the bone screws and plates would be used by doctors in spinal applications. J.A. 16-20.

In response to plaintiffs' "fraud on the FDA" allegations, Buckman contended that "intended use" is a term of art referring to the use for which the manufacturer seeks FDA clearance, as

determined by the indications for use claimed in the proposed labeling for the device, and does not encompass the manufacturer's subjective hopes, desires or expectations about how physicians, in the exercise of their independent medical judgment, might elect to use a device once it is on the market. Accordingly, Buckman argued that plaintiffs' state-law claim was preempted by the MDA, because it would impose disclosure requirements regarding a device's intended use that were "different from, or in addition to" (21 U.S.C. § 360k(a)) the disclosure requirements imposed by federal law.

Indeed, Buckman pointed out that it was *the FDA itself* that proposed, at the December 1985 meeting, that AcroMed separate the VSP into its component parts — the screw and the plate — and seek 510(k) clearance for each. Buckman submitted a memorandum written by FDA official Dan McGunagle, who had attended the meeting, in which McGunagle recalled:

> With the meeting at a stalemate I pointed out the FDA's long standing policy of evaluating (for not only substantial equivalence but safety and effectiveness) a device based on the labeling submitted for the device and the agreement between the labeling and the device's physical abilities to perform as the labeling claimed. I also pointed out that because of the physical and mechanical similarities between the plates and (the original design) screws of the system to ordinary bone plates and screws these devices, when labeled, indicated and promoted as simple bone screws and plates would, in fact, be substantially equivalent to pre-Amendment[ ] devices and could be shipped in interstate commerce. * * * I pointed to the oft stated FDA policy of not regulating the practice of medicine by individual physicians. I said that if individual practitioners, on their own without guidance from labeling or promotion by the manufacturer, chose to use the plates and screws for spinal fixation that would fall under the practice of medicine and outside FDA's authority.

J.A. 136.

In addition, Buckman explained that there was no possibility that the FDA had been misled about AcroMed's subjective hopes or desires that the screws, plates, rods, and hooks in the VSP and ISOLA Systems would be used by physicians in spinal applications. With regard to the VSP System, AcroMed had twice sought FDA clearance for spinal use; spinal applications had been discussed again at the December 1985 meeting; and shortly before the component plates and screws of the VSP gained 510(k) authorization, the company had asked the FDA for permission to begin clinical trials on the VSP System for spinal application. J.A. 13-16, 135-137. As for the ISOLA System, AcroMed had requested FDA approval to begin clinical trials concerning spinal use even before filing 510(k) notifications for individual components of the System. J.A. 17-18. In clearing the iliac screw component, the FDA had specifically directed the company to warn that it had "NOT BEEN APPROVED FOR PEDICULAR APPLICATION." J.A. 19.

2. *The District Court's Decisions*. In March 1995, the district court granted judgment on the pleadings on the "fraud on the agency" claim, holding that it was preempted both expressly by the MDA and impliedly by the federal scheme. Pet. App. 46a-53a. The district court explained that the MDA's express preemption provision "does not permit courts to 'perform the same functions initially entrusted to the FDA.'" *Id.* at 49a (quoting *Michael* v. *Shiley, Inc.*, 46 F.3d 1316, 1329 (3d Cir.), cert. denied, 516 U.S. 815 (1995)). Moreover, "[b]ecause the FDA possesses the proper authority to regulate this field, courts are prohibited from conducting 'a searching state inquiry into the inner workings of FDA procedures.'" *Ibid.* (quoting *Michael*, 46 F.3d at 1329); see also Pet. App. 50a (reasoning that, "given the FDA's central role in

reviewing and approving devices * * * [the agency] is in the best position to decide whether [a manufacturer] withheld material information from the agency and, if so, the appropriate sanction" (citation and internal quotation marks omitted)). Finally, the court noted that permitting "fraud on the agency" claims would be inconsistent with Congress's decision not to authorize a private right of action under the Food, Drug and Cosmetic Act. *Ibid.*

Following this Court's *Medtronic* decision in 1996, plaintiffs sought to revive their "fraud on the FDA" claim. Pet. App. 7a, 33a. Among other things, plaintiffs argued that their claim was not expressly preempted under *Medtronic* because it was seeking to enforce state requirements that were "identical" to the federal requirements and because the pertinent state and federal requirements relating to intended use disclosures were "general" in nature and thus not eligible for express preemption. Buckman responded that *Medtronic* did not involve a "fraud on the agency" claim and thus did not alter prior law in the Third Circuit (and in other jurisdictions) holding that such claims are preempted.

In March 1997, the district court reaffirmed its ruling that plaintiffs' "fraud on the agency" claim was preempted. Pet. App. 33a-44a. The court agreed that *Medtronic* had undercut portions of its previous analysis but held that the claim was still precluded because it was inconsistent with Congress's decision not to include a private right of action under federal law. *Id.* at 36a-37a. The court added that plaintiffs' claim was "not interchangeable" with the claims at issue in *Medtronic*, which involved no allegation of fraudulent procurement of agency clearance and therefore did not amount to a collateral attack on any agency decision. *Id.* at 40a.

Because "fraud on the FDA" was the sole claim against Buckman, the district court granted Buckman's motion for dismissal for failure to state a claim on which relief could be granted (Pet. App. 45a) and certified the dismissal as a final order under Rule 54(b) of the Federal Rules of Civil Procedure. Pet. App. 54a-56a.

D. The Court Of Appeals' Decision

A panel of the Third Circuit reversed, over a "vehement[]" (Pet. App. 32a) dissent by Judge Cowen. It concluded that *Medtronic* undermined the Third Circuit's previous holding in *Michael* that state "fraud on the FDA" claims are expressly and impliedly preempted. *Id.* at 13a-17a & n.5.

The court of appeals' reasons for rejecting express preemption were set forth in a single paragraph. According to the majority, the MDA did not expressly preempt "fraud on the FDA" claims because the 510(k) process does not establish *any* "federal 'requirement'" that is "'applicable to the device' at issue here." Pet. App. 13a. In equally sweeping fashion, the majority broadly declared that plaintiffs' common law fraud claim does not impose *any* "state 'requirement' 'with respect to' that device." *Ibid.* Finally, the majority reasoned that the state requirements plaintiffs sought to enforce do not "impose any obligation on Buckman [that is] inconsistent with federal law," because federal law prohibits making fraudulent statements to the FDA. *Ibid.*

The Third Circuit also rejected the argument that "fraud on the FDA" claims are impliedly preempted. Pet. App. 16a. The majority recognized that "Congress has not created an express or implied private cause of action for violations of the [Federal Food, Drug and Cosmetic Act (FDCA)] or the MDA." *Id.* at 13a. But it saw "no inconsistency" between Congress's decision to give the FDA the "exclusive prerogative" and discretion to enforce the requirements of federal law and allowing individuals to "bring common law fraudulent misrepresentation claims" to "enforce the FDCA." *Id.* at 18a. The majority relied as well on the "presumption against preemption" and the absence of express preemption of plaintiffs' claim, reasoning that *Medtronic* "teaches that where Congress has expressed its intention with respect to preemption, we should look primarily to what it said." *Id.* at 16a.

Judge Cowen dissented. Unlike the majority, he was troubled by permitting judges and juries hearing "fraud on the FDA" claims "to displace the FDA's judgment about whether a manufacturer has engaged in improper marketing." Pet. App. 32a. Judge Cowen also predicted that the majority's approach "will expose manufacturers to fraud liability for seeking desirable innovations in a product's use, distort the penalty scheme established by the FDCA and its regulations, and generate substantial liability when manufacturers respond to doctors' widely accepted practice of purchasing medical products for off-label uses." *Id.* at 25a.

E. The FDA's Reclassification Proceeding

Contemporaneous with these judicial proceedings, the FDA conducted a rulemaking in which it reclassified many of the bone screws challenged by plaintiffs from Class III to Class II when used to treat certain spinal conditions. See 60 Fed. Reg. 51946 (1995); 63 Fed. Reg. 40025 (1998). The FDA's decision, which followed an extensive review of the available medical data, was based upon its conclusion that special controls alone "would provide reasonable assurance of safety and effectiveness." 63 Fed. Reg. at 40025.

The plaintiffs in this case participated extensively in the FDA's reclassification proceeding. Plaintiffs' 231-page comments included the same "fraud on the agency" allegations that they advanced in the district court, accompanied by an 18-volume appendix consisting of more than 400 exhibits, many of which were drawn from discovery in this case. Comments by Plaintiffs' Legal Committee in *In re Orthopedic Bone Screw Prods. Liab. Litig.*, FDA Dkt. No. 95N-0176, at 17, 31-39 (filed March 1, 1996). In adopting its final rule, the FDA declined to credit plaintiffs' allegations and expressly rejected the argument that bone screws should be banned based on "deception." 63 Fed. Reg. at 40035-40036.

SUMMARY OF ARGUMENT

I. Plaintiffs' "fraud on the FDA" claim is expressly preempted by 21 U.S.C. § 360k(a). If allowed to proceed, it would impose *state* disclosure requirements relating to the "intended use" of the AcroMed medical devices that are materially different from the *federal* disclosure requirements relating to "intended use" that apply to the very same devices. The essential premise of plaintiffs' claim is that Buckman should have informed the FDA of AcroMed's subjective hopes, desires and expectations concerning how the devices might be used by physicians once they were on the market. Federal law imposes no such disclosure requirement in the 510(k) process.

Moreover, the state and federal disclosure requirements at issue in this case are "specific" in every relevant sense. They arise from the particularized application of state and federal laws to individual devices (and no others); they impose obligations to make specific disclosures that concern each device's "intended use"; and they are the product, on the federal side, of active and particularized review and consideration by the FDA.

II. Plaintiffs' "fraud on the FDA" claim is also impliedly preempted. Unlike the traditional state tort requirements involved in *Medtronic*, the gravamen of plaintiffs' claim is that petitioner Buckman *defrauded a federal agency*. That claim amounts to a collateral attack on the FDA's decision to clear the relevant devices for marketing. To prevail on their state-law claim, plaintiffs would have to show that the AcroMed devices should not have been on the market. But, from the perspective of the federal government, these devices *were* properly on the market. It is difficult to imagine a starker conflict between state and federal law. What is more, plaintiffs' claim would require a judge or jury, applying state law, to decide (1) what disclosures should have been made to the FDA, (2) whether Buckman satisfied those federal disclosure requirements, (3) whether the FDA already knew the information that was not disclosed, and (4) what the FDA would have done if

Buckman had disclosed the required information. The potential for second-guessing the FDA's own determinations of these issues is obvious.

Plaintiffs' "fraud on the FDA" claim also would conflict with the FDA's substantial interest in valid, final and correct decision-making as well as with Congress's intent to vest exclusive enforcement authority in the FDA. The claim would undermine the uniformity of federal law. And it would interfere substantially with federal government operations, by subjecting agency personnel to intrusive discovery, creating serious distortions in the FDA's regulatory process, and constricting the flow of medical information concerning off-label uses.

III. If the Court concludes that plaintiffs' "fraud on the FDA" claim is not preempted under current law, then it should reexamine *Medtronic*'s conclusion that the MDA's express preemption clause encompasses only "*specific* requirements" imposed by state and federal law. The concept of "specificity" is contrary to the plain language of Section 360k(a); is inherently ambiguous; has spawned enormous confusion and conflict in the lower courts; and has led to uncertainty and serious practical difficulties for device manufacturers. It is also based on an erroneous view of the FDA's past regulatory practice. The Court should eliminate this "utterly irrational loophole" (*Morales* v. *Trans World Airlines, Inc.*, 504 U.S. 374, 386 (1992)) from the law of MDA preemption.

ARGUMENT

In recent years, this Court has been called upon repeatedly to decide whether Congress, in enacting express preemption clauses aimed at safeguarding the exclusive authority of expert federal regulators and protecting interstate commerce from the burdens of excessive or divergent state regulation, meant to nullify state-law requirements that are imposed by judges or juries in private lawsuits. See, *e.g.*, *Geier* v. *American Honda Motor Co.*, 120 S. Ct. 1913 (2000); *Medtronic*, 518 U.S. 470; *Cipollone* v. *Liggett Group,*

Inc., 505 U.S. 504 (1992). That question has proved to be most nettlesome where the consequence of a finding of preemption is to deprive injured people of traditional remedies that they would otherwise have under state law against the manufacturers of dangerous or defective products.

This case is entirely different. The gravamen of plaintiffs' state-law claim is that certain participants in a federal regulatory process *defrauded the federal agency*. According to the plaintiffs, petitioner should have made certain disclosures and statements (and should not have made others) to the Food and Drug Administration in the course of seeking regulatory clearance to market certain medical devices. But it is hardly a traditional role of state law to police whether parties to a federal regulatory process comply with disclosure requirements imposed by a federal agency. Although state law generally includes protections against fraud, plaintiffs do not claim that *they* were defrauded; they claim that *the FDA* was defrauded.

This case accordingly bears no resemblance to the product liability suit in *Medtronic*, which involved routine state-law claims of design and manufacturing defects. This case also differs from *Medtronic* because preempting plaintiffs' claim here would not have "the perverse effect of granting complete immunity from design defect liability to an entire industry." 518 U.S. at 487. To the contrary, plaintiffs would still be able to bring product liability suits against the manufacturers, as well as fraud claims for representations made to them or to their physicians. Put another way, preemption here *would not eliminate any claim that plaintiffs would have had under state law if the MDA had not been enacted.* Indeed, plaintiffs' claim *could not exist* if there were no federal regulatory process in place; it is entirely dependent upon, and derivative of, a federal regulatory proceeding.

Plaintiffs' "fraud on the agency" claim is even more unlike a traditional tort action because, at bottom, it amounts to a collateral attack on the FDA's clearance decision. To prevail on their claim,

plaintiffs must prove that, but for Buckman's "fraudulent" submissions to the FDA, AcroMed's bone screws *would never have been cleared by the FDA* and thus would never have been used in plaintiffs' operations. To resolve plaintiffs' claim, then, a judge or jury — applying state law — must decide what information should have been submitted to the FDA and whether the agency, if it had received that information, would have reached a different result on AcroMed's 510(k) notifications. Traditional state-law product liability actions, in contrast, do not require judges and juries to step into the shoes and minds of federal regulators, interpret the scope of federal disclosure or other requirements, or second-guess decisions made by a federal agency.

For all of these reasons, plaintiffs' unorthodox claim is expressly as well as impliedly preempted by federal law. Plaintiffs' claim is expressly preempted because it imposes disclosure requirements with respect to medical devices that are plainly "different from, or in addition to" the disclosure requirements imposed by federal law. 21 U.S.C. § 360k(a). Plaintiffs' claim is impliedly preempted because it is a collateral attack on the marketing clearance decisions of expert federal regulators; it conflicts with Congress's decision to delegate to the FDA exclusive regulatory authority over the MDA (and Congress's corresponding decision *not* to create a private right of action under the MDA); it threatens the uniformity of federal law; and it creates distortions in the federal regulatory process, in the flow of information relating to off-label uses of devices, and in the agency's allocation of its own resources.

I. PLAINTIFFS' "FRAUD ON THE FDA" CLAIM IS EXPRESSLY PREEMPTED BECAUSE IT IMPOSES STATE-LAW DISCLOSURE REQUIREMENTS RELATING TO "INTENDED USE" THAT ARE "DIFFERENT FROM, OR IN ADDITION TO" THE DISCLOSURE REQUIREMENTS IMPOSED BY FEDERAL LAW

In enacting the MDA, Congress sought to preserve the uniformity of the federal regulatory scheme and to protect innovations in device technology from being "stifled by unnecessary restrictions" by including a "general prohibition on non-Federal regulation." H.R. REP. NO. 94-853, at 12, 45. That "general prohibition" was expressed in a broadly worded preemption clause:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use *any* requirement —
>
> (1) which is different from, or in addition to, *any* requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a) (emphasis added). The only exception to this sweeping command is for state requirements that the FDA elects to exempt from preemption pursuant to 21 U.S.C. § 360k(b).

Plaintiffs' "fraud on the agency" claim falls comfortably within the language of Section 360k(a). That claim rests entirely on the premise that state law required Buckman to make certain disclosures to the FDA about the "intended use" of the components of the VSP and ISOLA Systems. As discussed below, these state disclosure requirements are "different from, or in addition to," the disclosure requirements about "intended use" that are "applicable * * * to the device" under federal law. There is no dispute that the state requirements underlying plaintiffs' claim "relate[] to the

safety or effectiveness of the device or to any other matter included in a [federal] requirement applicable to the device"; plaintiffs have never suggested otherwise. Accordingly, this case presents a straightforward example of express preemption.

In *Medtronic*, a majority of this Court gave a limiting construction to the broad language of Section 360k(a). See 518 U.S. at 496-97. The majority relied, in turn, on a narrow interpretation of Section 360k(a) adopted by the FDA in setting forth the agency's procedures for considering exemptions from preemption. See 21 C.F.R. § 808.1(d). The Court also instructed that any inquiry into express preemption requires "a careful comparison between the allegedly pre-empting federal requirement and the allegedly pre-empted state requirement to determine whether they fall within the intended pre-emptive scope of the statute and regulations." 518 U.S. at 500. We accordingly explain, first, why the federal and state disclosure "requirements" involved in this case are different and, second, why those requirements fit within the ambit of Section 360k(a) as construed in *Medtronic*.

A. Plaintiffs Seek To Impose Disclosure "Requirements" That Are "Different From, Or In Addition To" The Disclosure "Requirements" Imposed By Federal Law

1. As an initial matter, we note that plaintiffs have never disputed that, at the time of the conduct giving rise to their claim, federal law imposed "requirements" on Buckman to make certain disclosures to the FDA in the 510(k) process involving the AcroMed devices. Indeed, plaintiffs have consistently maintained that Buckman violated the agency's disclosure requirements — an allegation that would make no sense if disclosure of the information specified in the agency regulations were *optional*. Although the parties vehemently disagree about what disclosures federal law

requires, there is no dispute that it *requires something*. This is not a case, then, where federal law imposes no requirement at all.[2]

Equally clear is the fact that plaintiffs' "fraud on the agency" claim, if allowed to proceed, would impose state-law "requirements" on Buckman concerning disclosures in FDA proceedings. In *Medtronic*, a majority of this Court held that state tort duties imposed through the common law constitute "requirements" within the meaning of Section 360k(a). See 518 U.S. at 509-511 (O'Connor, J., joined by Rehnquist, C.J., and by Scalia and Thomas, JJ., concurring in part and dissenting in part); *id.* at 504-505 (opinion of Breyer, J.). Indeed, Justice Breyer even gave as an example of a claim that would be preempted by the MDA "a state law tort action that premises liability upon the defendant manufacturer's failure to use a 1-inch wire," where "a federal MDA regulation requires a 2-inch wire." *Id.* at 504. Plaintiffs' "fraud on the agency" claim, which is similarly premised on state tort law, imposes "requirements" no less than does the state negligence or strict liability law in Justice Breyer's hypothetical.

2. These federal and state disclosure "requirements" are not "substantially identical." 21 C.F.R. § 808.1(d)(2). Plaintiffs' "fraud on the agency" claim is predicated on Buckman's purported

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[2] The Third Circuit apparently concluded otherwise, declaring that "[b]ased on *Lohr*, * * * there is *no* federal 'requirement' 'applicable to the device' at issue here." Pet. App. 13a (emphasis added). That rationale, however, indefensibly transforms this Court's determination in *Medtronic* that the 510(k) process imposes *no federal design "requirements"* into a holding that the 510(k) process imposes *no federal "requirements" at all*. See 518 U.S. at 493-494. The Third Circuit's logic also should be rejected because it would lead to ridiculous results. For example, Section 510(k) plainly requires that devices be "substantially equivalent" to pre-1976 devices in order to obtain marketing clearance. See 21 U.S.C. § 360e(b)(1)(B). Yet if Section 510(k) imposes no requirements at all, then the MDA would not preempt a state law that instead required a medical device to be "exactly identical" to a pre-1976 device before it could be marketed.

obligation, under state law, to disclose to the FDA that AcroMed subjectively desired or hoped that the bone screws, plates, rods, and hooks of the VSP and ISOLA Systems — although labeled for use only in bones other than the spine — would be used by physicians for spinal fixation. According to plaintiffs, if Buckman had disclosed this "true" subjective intent as it was required to do, the FDA would have refused to clear the 510(k) submissions and the VSP and ISOLA devices would not have been permitted onto the market. J.A. 21.

Federal law, in contrast, does *not* impose any requirement that a 510(k) submission disclose how a manufacturer subjectively intends that a device will be used, because subjective intent is irrelevant under the MDA. The FDA's regulatory authority extends *only* to the labeling and marketing of devices in interstate commerce and not to the practice of medicine (including off-label uses of approved drugs and devices). See 21 U.S.C. §§ 331(a), 396; 37 Fed. Reg. 16503, 16503 (1972) (objective of FDCA is "is to assure that drugs will be safe and effective for use under the conditions of use prescribed, recommended, or suggested in the labeling thereof," and regulatory authority does not extend to physicians' off-label use); *Pedicle Screws*, 24 FED. MED. BULL. 10 (May 1994) (noting that "pedicle screws may not be marketed" for spinal fixation because that indication for the devices has not yet been cleared by the FDA). So long as a device's labeling and a manufacturer's marketing refer only to cleared uses, the manufacturer has complied with the federal statute even if it hopes (as would any rational manufacturer) that physicians engage in off-label uses. See Nightingale, 26 DRUG INFO. J. at 141-143 (FDA Assoc. Comm'r for Health Affairs).

Under the 510(k) clearance process, the manufacturer determines the "intended use" for which it seeks FDA authorization to label and market a device. *That* use — not the use or uses for which the manufacturer hopes that physicians will employ the device — is what must be disclosed to the FDA and evaluated for "substantial equivalence" under Section 510(k). By imposing liability for

Buckman's failure to tell the FDA about AcroMed's *subjective* intent regarding its devices' use, state law would establish a disclosure requirement materially "different from, and in addition to" the requirements of federal law.

a. The statutory text strongly confirms our understanding of the scope of the federal disclosure requirement. In its current form, the MDA expressly provides that the "intended use" of a device in the 510(k) context is the use designated by the manufacturer in its submission to the FDA. The statute provides that "[a]ny determination by the Secretary of the intended use of a device," for purposes of determining whether the device is "substantially equivalent" to a pre-1976 device, "shall be based upon the proposed labeling" in the 510(k) submission. 21 U.S.C. § 360c(i)(1)(E)(i); see also S. REP. NO. 105-43, at 27 (1997) ("For premarket notification submissions, the labeling proposed in the submission will be controlling of a device's intended use."). The FDA may require a warning statement on the device's label against foreseeable uses that are potentially harmful — just as it did here, in requiring the statement "WARNING — THIS DEVICE HAS NOT BEEN APPROVED FOR PEDICULAR APPLICATION" to be included on labeling of the iliac screw that was part of the ISOLA System, see J.A. 19 — but it may not require the manufacturer to list those uses in its 510(k) submissions. See 21 U.S.C. § 360c(i)(1)(E)(i); S. REP. NO. 105-43, at 27.

Although this express statutory limitation of "intended use" postdates Buckman's 510(k) submissions, both Congress and the FDA have made clear that it corresponds to the original intent of Congress about how Section 510(k) should be applied. The committee report accompanying the clarifying amendment explains that it conforms to Congress's understanding of statutory requirements in enacting the MDA in 1976. See S. REP. NO. 105-43, at 27. The FDA has similarly noted that the statutory requirement that "intended use" for Section 510(k) be determined by the use listed in proposed labeling "is not different from the manner in which 510(k)s have traditionally been reviewed." U.S. Dep't of Health &

Human Servs., Food & Drug Admin., Office of Device Evaluation, Center for Devices and Radiological Health, *Determination of Intended Use for 510(k) Devices — Guidance for Industry and CDRH Staff* 1 (Jan. 30, 1998); cf. 21 U.S.C. § 360c(a)(2)(B) ("safety and effectiveness of a device are to be determined * * * with respect to the conditions of use prescribed, recommended, or suggested in the labeling of the device"); *id.* § 355(d)(1).

b. Prior FDA pronouncements and applications of the statute are consistent with the principle that the intended use of a device for 510(k) purposes is determined by labeling claims rather than by the manufacturer's subjective intent. Thus, an FDA official explained in 1989 that determining whether the "intended use" of a device is substantially equivalent to that of a predicate device is established by asking whether the new device has the "Same Indication Statements" as the pre-1976 device. Callahan, *The Process of FDA Approval of a Spinal Implant: Governmental Perspective*, 2 J. SPINAL DISORDERS 288, 289 (1989); accord Center for Devices and Radiological Health, Food & Drug Admin., Premarket Notification Review Program, 510(k) Memorandum #86-3 (June 30, 1986) (reprinted at <http:/www.fda.gov/cdrh/k863.html>). "When the FDA approves products," the agency official noted, "it does so on a device-by-device basis *for specific intended uses* and not in general terms, e.g., pedicle spinal fixation systems." Callahan, 2 J. SPINAL DISORDERS at 29[illegible] (emphasis added); see also, *e.g.*, 57 Fed. Reg. 18062, 18063 (1992) ("[i]n determining whether the new device has the same intended use as a predicate device" under Section 510(k), FDA assesses "any differences in *indications for use* in terms of the safety and effectiveness questions they may raise" (emphasis added)); 63 Fed. Reg. 64556, 64560 (1998) (noting that new "intended use" is created when device previously marketed for general use is labeled for use on specific body part).

Indeed, the FDA regulation governing device labeling expressly provides that "intended use" "refer[s] to the *objective intent*

of the persons legally responsible for the labeling of devices," as manifested by "labeling claims, advertising matter, or oral or written statements." 21 C.F.R. § 801.4.[3] Although a manufacturer may be required to include warnings in its labeling informing customers of dangerous off-label uses, see *ibid.*, there is *no* FDA requirement that a manufacturer seek FDA clearance for all foreseeable uses by listing them in its 510(k) submission.

c. Determining substantial equivalence under 510(k) by reference to a manufacturer's subjective intent is also difficult to reconcile with the nature of the 510(k) process itself. The substantial equivalence inquiry under 510(k) is necessarily comparative in nature: the 510(k) device must "ha[ve] the same intended use as the predicate device." 21 U.S.C. § 360c(i)(1)(A); see also 21 C.F.R. § 807.100(b)(1). But the FDA would have no way of knowing how the manufacturer of a predicate device subjectively intended for it to be used prior to 1976 (or for that matter what the manufacturer's subjective intent is today, because the FDA does not require manufacturers to seek clearance of new off-label uses for devices that are already on the market).[4] Accordingly, the intended use of the predicate device must necessarily be judged by its *labeling claims*. Under plaintiffs' theory, the FDA would have to apply one standard of "intended use" to the predicate device and another,

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[3] By its terms, the definition of "intended use" in Section 801.4 does not apply to 510(k) premarket notifications. Compare 21 C.F.R. § 801.4 (defining "intended uses" and similar words "in §§ 801.5, 801.119, and 801.122"), with *id.* § 807.87 (governing information required in a premarket notification submission, including "[p]roposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use"). Nonetheless, Section 801.4 confirms that "intended use" in the MDA does not refer to a manufacturer's subjective intent.

[4] The FDA's longstanding position has been that "the decision about whether or not, and when" to apply for approval of off-label uses is the manufacturer's alone to make. Nightingale, 26 DRUG. INFO. J. at 142.

quite different standard to the device for which 510(k) clearance is being sought. There is no basis for such an anomalous result.

d. Plaintiffs' subjective standard also undermines the basic purpose underlying Section 510(k), which is to ensure that pre-1976 devices are not insulated from competition by later market entrants. Plaintiffs' definition of intended use would mandate rejection of new devices based on vague notions of subjective intent. That, in turn, would have the effect of impeding competition even where the proposed 510(k) device has the same labeling claim as a predicate, pre-1976 device to which the proposed device is substantially equivalent. There is no reason to think that Congress meant to enhance competition only where manufacturers of 510(k) devices have no subjective hope, desire, or expectation that their devices, once cleared, might be used by physicians for some off-label use.

e. Finally, plaintiffs' definition of intended use would be wholly unworkable in practice. Plaintiffs have not explained, for example, *whose* subjective intent would have to be disclosed to the FDA. If a corporate director intended one use for a device, while the marketing director intended another, which would be subject to mandatory disclosure to the FDA and govern the substantial equivalence inquiry? Cf. 21 C.F.R. § 801.4 (defining intended use for labeling purposes as "objective intent of *persons* legally responsible for the labeling of devices" (emphasis added)). What if corporate officials intended primarily that the device would be used in a well-established manner, but hoped for eventual acceptance of a now-experimental methodology? Would it make any difference if the company's subjective intent changed between the time it filed the 510(k) notification and the FDA's clearance of the device for marketing? These questions demonstrate why 510(k) disclosure requirements focus on how a device will be labeled and do not extend to a manufacturer's subjective intent or hope about how a device might be used.

B. The State "Requirements" Underlying Plaintiffs' Claim Qualify For Express Preemption Under *Medtronic*

Section 360k(a) covers "any [state or local] requirement" that "relates" either "to the safety or effectiveness of the device or to any other matter included in a [federal] requirement applicable to the device." There can be no doubt that the state requirements in this case "relate" to safety and effectiveness concerns. They also plainly relate to a "matter" that is "included in" a counterpart federal requirement — disclosures concerning the device's "intended use." See 21 C.F.R. § 807.87(e) (1986, 1999). The state "requirement" in this case accordingly comes within the plain language of the MDA's express preemption clause.

The FDA, however, has taken the position that Section 360k(a)'s broad reference to "*any* requirement" should be interpreted as meaning "any *specific* requirement." See 21 C.F.R. § 808.1(d). In *Medtronic*, a majority of this Court appeared to endorse the FDA's "specificity" gloss on the statutory text. Compare 518 U.S. at 500, 506-507, with *id.* at 512 (O'Connor, J., joined by Rehnquist, C.J., and by Scalia and Thomas, JJ., concurring in part and dissenting in part) ("The statute makes no mention of a requirement of specificity, and there is no sound basis for determining that such a restriction on 'any requirement' exists."). Whether *Medtronic*'s *actual holding* turned on the absence of specificity in the *state* requirements involved in that case is not altogether clear for at least two reasons.

First, the same majority that appeared to endorse "specificity" in *Medtronic* elsewhere declared: "[W]e do not believe that th[e] statutory and regulatory language necessarily precludes 'general' federal requirements from ever pre-empting state requirements, or 'general' state requirements from ever being pre-empted." 518 U.S. at 500. That statement, of course, reflects a *rejection* of the idea that requirements under Section 360k(a) are preempted or preemptive only if they are "specific."

Second, the overriding focus of Justice Breyer's tie-breaking opinion was almost exclusively on the pertinent *federal* (as opposed to the *state*) requirements. 518 U.S. at 507 (Breyer, J.) ("Insofar as there are any applicable *FDA requirements here,* those requirements, even if numerous, *are not 'specific' in any relevant sense*." (emphasis added)). Since Justice Breyer's resolution of the case turned on the character of the *federal* requirements at issue, which he concluded were too general to trigger preemption, he had no occasion to resolve whether express preemption under the MDA also requires specificity on the *state* side. Accord *Papike* v. *Tambrands, Inc.*, 107 F.3d 737, 742 (9th Cir.) ("Although Justice Breyer joined in Section V [of Justice Stevens' opinion], * * * it is clear enough that the Court found no preemption of the common-law claims largely because the pacemaker was not subject to any device-specific FDA regulations."), cert. denied, 522 U.S. 862 (1997).

In any event, the state requirements underlying plaintiffs' claim satisfy any "specificity" gloss that might apply. In sharp contrast to *Medtronic*, where "the precise contours of [plaintiffs'] theory of recovery" had "not yet been defined" (518 U.S. at 495), plaintiffs' "fraud on the agency" claim has been set forth in minute detail in their complaint (see J.A. 13-21), as required by Fed. R. Civ. P. 9(b). Plaintiffs allege that Buckman and AcroMed should have made specific disclosures to the FDA in connection with the 510(k) submissions they made for the components of the VSP device and ISOLA Systems. In particular, plaintiffs claim that Buckman was required to state precisely that AcroMed had a subjective desire or intent that each of these devices would be used by physicians in spinal applications. That claim is just as "specific" as Justice Breyer's example of a claim based on the manufacturer's failure to use a 1-inch wire. Indeed, a more precise formulation of the "liability-creating premises" of a plaintiff's "state-law tort suit" (518 U.S. at 508 (Breyer, J.)) is difficult to imagine. See *Mitchell* v. *Collagen Corp.*, 126 F.3d 902, 912 (7th Cir. 1997), cert. denied, 523 U.S. 1020 (1998).

The state laws underlying plaintiffs' claim have also been applied with specificity to each of the AcroMed devices, thus satisfying the "specificity" concept expressed in the FDA's regulation, 21 C.F.R. § 808.1(d)(1). At some point in the course of litigation, the general duties that are the basis of a plaintiff's tort claim become applied with specificity to a particular product that is at issue in the lawsuit. As the United States recognized in its brief at the petition stage, when that occurs "a specific duty of care" is "made applicable to a device through a State's common law of torts," and that duty gives rise to a "requirement" within the meaning of the MDA's express preemption clause. U.S. Br. 10 n.4. That plainly has occurred in this case. Plaintiffs' claim thus imposes state-law requirements that are "specific" in every relevant sense.

The Third Circuit was accordingly wrong to conclude that "[b]ased on *Lohr* * * * there is no * * * state 'requirement' 'with respect to'" AcroMed's medical devices. Pet. App. 13a. To the extent that the court of appeals read *Medtronic* as shielding all common law claims "of general applicability" from express preemption, it simply misread the case.

C. The Counterpart Federal "Requirements" Involved In This Case Trigger Express Preemption Under *Medtronic*

The federal disclosure requirements at issue in this case are derived from FDA regulations in effect at the time Buckman submitted 510(k) notifications for the devices comprising the VSP and ISOLA Systems. Those regulations, which remain in force today, mandated the disclosure for proposed 510(k) devices of "the following information: * * * (e) Proposed labels, labeling, and advertisements *sufficient to describe* the device, *its intended use*, and the directions for its use." 21 C.F.R. § 807.87(e) (1986, 1989) (emphasis added). The FDA's regulations also required regulated entities to supply "[a]ny additional information regarding the device requested by the Commissioner to make a finding as to whether or not the device is substantially equivalent to a device in commercial distribution." 21 C.F.R. § 807.87(h) (1986, 1989).

Buckman complied with the standard disclosure requirements by submitting detailed information about the screws, plates, hooks and rods of the VSP and ISOLA Systems (and the pre-1976 devices to which those devices were substantially equivalent) in its 510(k) submissions. See J.A. 48-51, 54-57. These submissions included information about each device's intended use. See J.A. 51, 57. Moreover, according to plaintiffs' own complaint, the FDA informed Buckman, following the submission of AcroMed's 510(k) notifications relating to the VSP System, that there was a "need for a more definitive statement covering the intended 'indications for use' of the AcroMed Nested Bone Plate." J.A. 15-16, 57-58. Buckman sent a letter in response to this agency demand for more information, stating (J.A. 58):

> The proposed indications for use for the AcroMed device are the same general indications proposed for the AO system of plates. More specifically, (for the purpose of this 510K), the AcroMed plates are intended for use in appropriate fractures of long bones of both the upper and lower extremity and such other flat bones (as in the fractured pelvis) that may from time to time require stabilization with contourable metallic non-compressing plates.

It is beyond dispute that all of these disclosures were *required* by federal law.[5]

In addition, the federal disclosure requirements imposed on Buckman in this case were "specific" in every relevant sense. See

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[5] In its cursory comparison of the state and federal requirements at issue, the Third Circuit misidentified the pertinent federal requirements as those imposed by 18 U.S.C. § 1001 and 21 C.F.R. § 807.87(j), which "make[ ] it a crime to make a fraudulent statement to a federal agency and * * * require[ ] every premarket notification to contain a statement that the information contained therein is believed to be truthful." Pet. App. 13a. The Third Circuit's reliance on 21 C.F.R. § 807.87(j) is especially puzzling, because that provision did not even exist at the time that the pertinent 510(k) submissions were made in 1985 and 1988.

21 C.F.R. § 808.1(d). The FDA's regulation requiring disclosure of a device's intended use in any 510(k) submission (21 C.F.R. § 807.87(e) (1986, 1989)) was applied with particularity to each of the AcroMed devices. Moreover, the FDA regulation requiring the disclosure of information specifically requested by the agency (21 C.F.R. § 807.87(h) (1986)) was applied to the AcroMed Nested Bone Plate when the agency demanded more detailed disclosures about that device. These federal disclosure requirements narrowly and specifically focused upon "intended use" disclosures concerning *these particular devices*. And, in response to these federal requirements, Buckman and AcroMed made detailed and particularized statements about the intended use of the individual devices — again, disclosures *required* by federal law. The applicable federal requirements, in short, were "specific" in their content as well as in their application to *these* devices. See 21 C.F.R. § 808.1(d) ("State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other *specific* requirements applicable to *a particular* device under the act * * *." (emphasis added)). They plainly trigger preemption under Section 360k(a).

This case presents an especially strong one for preemption because of the active role played by the FDA in requiring Buckman to make disclosures about the "intended use" of the AcroMed devices. It is undisputed that the FDA met with Buckman and AcroMed in December 1985 specifically to discuss the "intended use" of the VSP System. It is also undisputed that after Buckman submitted the 510(k) notifications for the VSP, the FDA reviewed those submissions and requested a more detailed disclosure, which was provided. With respect to the ISOLA System, moreover, plaintiffs allege that FDA officials engaged Buckman in discussions about whether the various 510(k) devices could be combined into a single 510(k) submission. J.A. 18. Plaintiffs also allege that the FDA, in authorizing the marketing of the iliac screw, imposed a specific warning requirement that plainly indicated an awareness of the possibility that some physicians might use the screw in pedicle applications. J.A. 19.

Thus, unlike in *Medtronic*, where the Court found that federal labeling and good manufacturing practices (GMP) requirements that applied generally to all medical devices did not trigger preemption, this is

> a case in which the Federal Government has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved * * *, and implemented that conclusion via a specific mandate on [the] manufacturer[ ].

518 U.S. at 501.[6]

In sum, through the 510(k) clearance process, FDA officials applied the "intended use" disclosure requirements with particularity to the *specific* AcroMed devices involved in this case in a manner that produced *specific* disclosures. Thus, even as construed in *Medtronic*, Section 360k(a) plainly preempts plaintiffs' "fraud on the agency" claim.

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[6] The federal labeling regulations at issue in *Medtronic* also are distinguishable because they apply, "with a few limited exceptions," to "every medical device." 518 U.S. at 497; see also *ibid.* (noting broad applicability of GMPs). In contrast, the FDA's disclosure requirements involved in this case are limited to devices for which 510(k) clearance is sought. The FDA has acknowledged that "specific FDA requirements applicable to a particular device *or class of devices*" trigger express preemption under the MDA. 43 Fed. Reg. 18661, 18662 (1978) (emphasis added); see also *id.* at 18664 (federal requirements that apply to PMA devices trigger express preemption); 45 Fed. Reg. 67321, 67322 (1980) (federal GMP regulations trigger preemption under the MDA).

II. PLAINTIFFS' "FRAUD ON THE FDA" CLAIM IS IMPLIEDLY PREEMPTED BECAUSE IT IS FLATLY INCONSISTENT WITH THE FEDERAL REGULATORY SCHEME

The only basis for plaintiffs' claim against Buckman is that the FDA should not have cleared AcroMed's devices for sale under Section 510(k). Plaintiffs do not contend that Buckman is liable because the devices were defectively designed or manufactured; as a consultant to AcroMed, involved solely in the regulatory process, Buckman had nothing to do with device design or manufacture. Nor do plaintiffs contend that Buckman is liable because the devices were marketed for an unapproved use, undoubtedly because Buckman had no involvement in marketing. Plaintiffs assert, instead, that Buckman fraudulently misrepresented the intended use of AcroMed's devices in its submissions and statements to the FDA and that, but for this fraud, "the FDA would not have issued 510(k) clearances for AcroMed's pedicle screw fixation devices for any purpose, the devices would not have been introduced into interstate commerce, and [individual plaintiffs] would not have been exposed to the dangerous device[s] which [were] surgically implanted" in their spines. J.A. 21. Plaintiffs' injuries thus derive entirely from the FDA's decision to allow AcroMed's devices to be marketed; that is the sole error they challenge here.

Plaintiffs' attack on the FDA's decisional process intrudes on an area "so 'intimately blended and intertwined with responsibilities of the national government' that its nature alone raises an inference of exclusion" of state law. *Bethlehem Steel Co.* v. *New York State Labor Relations Bd.*, 330 U.S. 767, 772 (1947) (quoting *Hines* v. *Davidowitz*, 312 U.S. 52, 66 (1941)); see also *United States* v. *Locke*, 120 S. Ct. 1135, 1147 (2000); *Boyle* v. *United Technologies Corp.*, 487 U.S. 500, 507 (1988). The basic premise of plaintiffs' claim is that the States must oversee (and occasionally override) federal agencies' decisions to ensure faithful execution of the agencies' duties. Yet the relationship between a federal agency and the entities it regulates is a matter solely of

federal concern, governed solely by federal law. The terms of the interaction between a federal agency and regulated entities — including what the entities must disclose to the agency and how those disclosures must be made — are determined entirely by agency-set and agency-enforced rules and requirements. And because it is interests protected by the federal agency that are at stake, the agency is best able to vindicate those interests when its rules and requirements are violated. See Pet. App. 50a (FDA "is in the best position to decide whether [a manufacturer] withheld material information from the agency and, if so, the appropriate sanction" (citation and quotation marks omitted)). The States have *no* role in policing this area.[7]

Predictably, then, state "fraud on the agency" claims would have substantial adverse effects on federal law and policy. If permitted, plaintiffs' claim would undermine the validity and finality of agency decisions and threaten the interests that underlie those decisions; conflict with Congress's intent that the MDA be administered exclusively by the FDA and with the FDA's own claim of primary jurisdiction over regulated matters; contravene the FDA's decision to permit AcroMed to market its devices notwithstanding plaintiffs' allegations of fraud; and interfere substantially with FDA operations by encouraging regulated entities to flood the agency with unwanted information and by embroiling the agency and its employees in private litigation. Thus, regardless of whether plaintiffs' "fraud on the agency" claim is expressly preempted, it is impliedly preempted because it would "actually conflict" with federal law (*Fidelity Fed. Sav. & Loan Ass'n* v. *de la Cuesta*, 458 U.S. 141, 153 (1982)) and would "stand[

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[7] The uniquely federal interests at stake render inapplicable the "presumption against preemption of areas traditionally occupied by state law," on which the court below relied. See Pet. App. 18a. There is *no* tradition of State oversight of compliance with federal regulations governing submissions to federal agencies (or, indeed, with any other regulations governing the relationship between federal agencies and regulated parties). In fact, plaintiffs' "fraud on the agency" claim *would not even exist* but for federal law.

as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Freightliner Corp.* v. *Myrick*, 514 U.S. 280, 287 (1995) (citation and quotation marks omitted); see *Geier*, 120 S. Ct. at 1922; *Boggs* v. *Boggs*, 520 U.S. 833, 841 (1997).

A. "Fraud On The Agency" Claims Conflict With Federal Agencies' Interest In Valid, Final, And Correct Decisionmaking

1. Our federalist system rests on the principle that "[a] state court may not decline to give effect" to a valid decision of the federal government. U.S. Br. 16 (petition stage). As the Solicitor General has observed, a federal agency's decisions "should generally be questioned or set aside, if at all, only by the federal government itself." *Ibid.*

"Fraud on the agency" claims contravene this basic principle. To prevail on their claim, plaintiffs must obtain a determination under *state law* that AcroMed's devices are illegally on the market, even though the FDA has conclusively determined, under *federal law*, that they should be on the market. States lack this "virtual power of review" over federal agency decisions. *Leslie Miller, Inc.* v. *Arkansas*, 352 U.S. 187, 190 (1956); see *Bethlehem Steel*, 330 U.S. at 775-776. It is difficult to imagine a greater conflict between state and federal law.

2. In addition to its interest in the validity of its own decisions, the federal government has a "significant interest in the[ir] *finality*." U.S. Br. 16 (petition stage) (emphasis added). If plaintiffs and similarly situated litigants were permitted to pursue "fraud on the agency" claims, "federal regulatory decisions that Congress intended to be dispositive would merely be the first round of decision making, with later more important rounds to be played out in the various state courts." *Lewis* v. *Brunswick Corp.*, 107 F.3d 1494, 1505 (11th Cir. 1997), cert. dismissed, 523 U.S. 1113 (1998). Binding federal decisions should not be vulnerable to state-law collateral attacks brought years or even decades later.

3. "Fraud on the agency" claims require a judge or jury, applying state law, to decide (1) the scope of the federal duty involved; (2) whether that duty was met; and (3) if not, what the federal agency would have done had it been met. Permitting courts to engage in this inquiry under state law — in particular, determining what a federal agency would have done under different circumstances — creates an unacceptable potential for conflict with the agency's own assessment of federal interests.

A judge or jury asked to guess what an agency would have done in a particular factual scenario would have to speculate about the agency's likely rationale and the relative weight that would be given to different decisional factors — all without the benefit of agency expertise. In many cases, the jury would arrive at decisions at odds with the decision the agency itself would have reached. A jury applying state law might conclude, for example, that a particular device as to which certain disclosures were not made should not have been allowed on the market, whereas the FDA might have determined that the nondisclosures were not material or that, despite the violation, the public health required that the device be available. This unacceptable risk of conflict with federal interests is endemic to state-law claims based on speculation about what a federal agency would have done under different circumstances.

B. "Fraud On The Agency" Claims Conflict With The MDA Statutory Scheme

1. State second-guessing of FDA decisions is particularly troubling under the regulatory regime at issue in this case. The MDA strikes a careful balance between shielding the public "against unsafe, unproven, ineffective, and experimental medical devices" and ensuring that progress in the development of medical devices is not "stifle[d]" by "excessive or ill-conceived" regulation. H.R. REP. NO. 94-853, at 10; see also *FDA Oversight: Medical Devices: Hearing before the Subcomm. on Oversight and Investigations of House Comm. on Energy & Commerce*, 97th Cong., 2d Sess. 5 (1982). A key element in striking this balance is Congress's delegation of *exclusive* authority to the FDA.

Permitting state review and nullification of FDA enforcement decisions runs roughshod over this carefully calibrated enforcement scheme.

The FDA is expressly charged with determining when and how to enforce the Food, Drug and Cosmetic Act, including the MDA. See 21 U.S.C. §§ 371(a), (h), 393; *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 627 (1973). The FDA has exercised this authority by taking "primary jurisdiction" over all "issues within its statutory mandate," including the decision "whether a device that is marketed for the first time after May 28, 1976, is substantially equivalent to a previously marketed device." 21 C.F.R. § 10.25(b); 41 Fed. Reg. 37457, 37459 (1976); see also H.R. REP. NO. 94-853, at 13. The FDA's domain extends not only to the "initial determination" of these issues, but also to previous decisions that "the agency conclude[s] should be reconsidered." 21 C.F.R. § 10.25(b).

The FDA's enforcement authority is marked by "complete discretion" in responding to statutory or regulatory violations. *Heckler* v. *Chaney*, 470 U.S. 821, 835 (1985); see also 21 U.S.C. § 336 (FDA need not seek sanctions for minor violations of FDCA where it "believes that the public interest will be adequately served by a suitable written notice or warning"). Although the FDA typically withdraws clearance of a device upon learning that it was obtained through fraud or misrepresentation, the agency may choose not to overturn its prior decision if, in its view, public health or other considerations support another course of action. See 56 Fed. Reg. 46191, 46192-46194, 46197 (1991); 55 Fed. Reg. 52323, 52324 (1990).

The broad enforcement discretion given to the FDA is combined with an express exclusion of other would-be litigants. Thus, unlike under the securities law, the antitrust laws, and many other federal regulatory schemes, there is no express or implied private right of action under the FDCA. See *Medtronic*, 518 U.S. at 487. To the contrary, "all * * * proceedings for the enforcement, or to restrain violations, of [Title 21, Chapter 9] shall be by and in the name of the United States." 21 U.S.C. § 337(a). Although States

are expressly permitted to enforce a small set of provisions (not including Section 510(k)), they may do so only after giving advance notice to the FDA so that the agency can decide whether to bring its own enforcement action or to intervene in the state proceedings. 21 U.S.C. § 337(b). The only mechanism for individual enforcement of the MDA is a citizen petition to the FDA. 21 C.F.R. §§ 10.25(a), 10.30(e).

Plaintiffs' "fraud on the FDA" claim cannot be reconciled with Congress's reservation of exclusive enforcement authority to the FDA or with the FDA's own claim of primary jurisdiction. As this Court recognized in *Merrell Dow Pharmaceuticals, Inc.* v. *Thompson*, 478 U.S. 804 (1986), in the absence of a private right of action to enforce a federal statute, it would "flout, or at least undermine, congressional intent to conclude that the federal courts might nevertheless * * * provide remedies for violations of that federal statute." *Id.* at 812. In fact, the effect of plaintiffs' "fraud on the agency" claim in this case "is exactly the same as it would be if a state court determined that an implied right of action was created by a federal statute." Sherman, *Use of Federal Statutes in State Negligence Per Se Actions*, 13 WHITTIER L. REV. 831, 890, 902 (1992).

By infringing on the FDA's exclusive authority to decide whether a device is substantially equivalent to a pre-1976 device and to respond to fraud or misrepresentation in the clearance process, and by asking a court to nullify an FDA decision under state law, plaintiffs' claim "interferes with the methods by which the [MDA] was designed" to be carry out Congress's goals. *International Paper Co.* v. *Ouellette*, 479 U.S. 481, 494-495 (1987); see also *Gade* v. *National Solid Wastes Management Ass'n*, 505 U.S. 88, 103-104 (1992) (plurality); *Allis-Chalmers Corp.* v. *Lueck*, 471 U.S. 202, 211 (1985). The Supremacy Clause does not permit a court applying state law to "usurp[] a function that Congress has assigned to a federal regulatory body." *Arkansas-Louisiana Gas Co.* v. *Hall*, 453 U.S. 571, 580-582 (1981).

2. The Third Circuit recognized that there was no private right of action under the FDCA, but held that, under *Medtronic*, this

could not be a basis for implied preemption. See Pet. App. 15a. The court of appeals reasoned that the *Medtronic* plurality had "viewed Congress' failure to provide a federal remedy [under the FDCA] as persuasive evidence of an intent not to preempt common law liability for the same conduct." *Ibid.* Given the *Medtronic* plurality's conclusion that Section 360k(a) did not bar "'a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements,'" the court explained, "[r]efusing to entertain Buckman's fraudulent misrepresentation claim solely because the statutory scheme does not contain a private cause of action would be * * * contrary to [*Medtronic*'s] clear holding." Pet. App. 16a (quoting *Medtronic*, 518 U.S. at 495).

The Third Circuit's reasoning suffers from several fatal flaws. To begin with, the language quoted from *Medtronic* was concerned entirely with the applicability of *express* preemption of common law claims under 21 U.S.C. § 360k(a). This Court had no occasion in *Medtronic* to consider the consequences for *implied* preemption of Congress's decision to preclude a private right of action under the FDCA. Indeed, even the Justices who concluded that express preemption did not apply agreed that a common law claim might nonetheless be *impliedly* preempted because of its conflict with the federal regulatory scheme. 518 U.S. at 503, 508.

Moreover, and more important, *Medtronic* did not involve a "fraud on the agency" claim, which is qualitatively different from the routine product liability claims that were then before the Court. *Medtronic* upheld against preemption "a traditional damages remedy for violations of common-law duties," so long as those duties "parallel federal requirements." 518 U.S. at 495. Common law claims alleging liability for design defect or negligent manufacture — *i.e.*, claims like the ones in *Medtronic*, *id.* at 481 — are within the core of the State's police power. They rest on *state*-imposed duties of care, derived from *state* standards. They do not require a state judge or jury to evaluate the wisdom of the FDA's decision to grant marketing clearance under 510(k), and a judgment

in favor of the plaintiff would not reflect on the FDA's decisional process.

The claim at issue here is of a very different sort. It involves the FDA's enforcement of its requirements governing the federal regulatory process, an area of longstanding and exclusive *federal* authority. It seeks to impose liability for violation of a duty imposed by *federal*, not state, law. And the crux of the claim is a challenge to the propriety of an FDA clearance decision and the integrity of the FDA decisional process. In this sense, plaintiffs' "fraud on the agency" claim is similar to a claim challenging a device's 510(k) clearance on the grounds that the employee responsible for the decision was not hired in accord with FDA requirements. Like the FDA's compliance with its own internal hiring policies, Buckman's compliance with FDA regulatory requirements is an area of exclusively federal concern, properly policed by the agency itself and not by judges and juries applying the laws of the 50 States.

Congress's decision to centralize all FDCA enforcement authority in the FDA, and to preclude private rights of action to enforce the *federal statute*, might not be frustrated by allowing traditional *state law* claims, such as those involved in *Medtronic*, to proceed. But it is quite another matter to allow plaintiffs' "fraud on the agency" claim, which (while nominally based on state law) could not exist apart from the FDCA, which seeks to enforce requirements imposed by the FDCA, and which in essentially all respects is indistinguishable from a private cause of action under the FDCA.

3. The very purpose of the FDCA's exclusive enforcement scheme is to ensure consistency and uniformity of interpretation. As this case demonstrates, "[a] multiplicity of tribunals and a diversity of procedures are quite as apt to produce incompatible or conflicting adjudications as are different rules of substantive law." *Garner* v. *Teamsters Local Union No. 776*, 346 U.S. 485, 490-491 (1953). A judge or jury asked to reevaluate an FDA decision under state law may have to consider events going back years or even decades; with "regulatory and scientific approaches [changing]

over time," "[a]ctions or choices that may seem clear today may have been less obvious to the decision makers involved in the issues at the time decisions were being made." FOOD & DRUG ADMIN., REPORT OF THE HALCION TASK FORCE i (1996).

In this case, the potential inconsistency has become actual. Plaintiffs pursue a "fraud on the FDA" claim despite the fact that the FDA has already thoroughly considered their allegations of fraud *and concluded that AcroMed's devices should remain on the market*. As noted above (at 11-12), plaintiffs submitted lengthy comments in recent FDA proceedings to reclassify bone screws, in which plaintiffs raised each of their allegations of fraud against Buckman; after reviewing the evidence, the FDA nonetheless decided that — far from being removed from the market — bone screws should be subject to *less* regulation and labeled for use in the spine. "It is difficult to escape the conclusion that the [state] litigation [is] * * * an attempt by a disappointed [litigant] to gain from the [state] courts the relief it was denied by the [federal agency]," a result barred by the Supremacy Clause. *Chicago & N.W. Transp. Co.* v. *Kalo Brick & Tile Co.*, 450 U.S. 311, 324, 326-327 (1981); see also *Schneidewind* v. *ANR Pipeline Co.*, 485 U.S. 293, 310 (1988); *Nantahala Power & Light Co.* v. *Thornburg*, 476 U.S. 953, 968-969 (1986).

4. The express preemption provision in the MDA, like those in many other statutes,[8] manifests Congress's intent to shield

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[8] Numerous federal regulatory statutes contain express preemption provisions similar or identical to Section 360k(a). *E.g.*, FIFRA, 7 U.S.C. § 136v(b); Flammable Fabrics Act, 15 U.S.C. § 1203(a); Federal Hazardous Substances Act, *id.* § 1261 note (b)(1)(A); National Traffic and Motor Vehicle Safety Act, *id.* § 1392(d); Poison Prevention Packaging Act, *id.* § 1476(a); Consumer Product Safety Act, *id.* § 1075(a); Electronic Product Radiation Control Act, 21 U.S.C. § 360ss; Federal Boat Safety Act, 46 U.S.C. § 4306. "Fraud on the agency" claims have been brought under many of these statutes as well. *E.g.*, *Lewis*, 107 F.3d at 1505; *Welchert* v. *American Cyanamid*,

(continued...)

regulated entities against inconsistent state laws. Yet "[v]irtually any federal agency decision that stood in the way of a lawsuit could be challenged indirectly by a claim that the industry involved had misrepresented the relevant data or had otherwise managed to skew the regulatory result." *Lewis*, 107 F.3d at 1505. Under the MDA and analogous federal statutes, "fraud on the agency" claims thus provide a ready means to circumvent almost any preemptive federal requirement. "Congress could not have intended for the process it so carefully put in place" by adopting express preemption provisions "to be so easily and thoroughly undermined." *Ibid.*

Even unsuccessful claims of "fraud on the agency" impose tremendous burdens on regulated entities. Allegations of incomplete disclosure in the MDA context, for example, can trigger burdensome, intrusive, and expensive discovery into product development files, covering multi-year periods and evolving scientific evaluations of complex formulas and patient reactions. Often, such claims can be rejected only after a full trial. And of course, companies may be charged with "fraud on the agency" not just by disgruntled consumers but also by industry competitors. Suits such as these, which represent collateral attacks on agency decisions, cannot be reconciled with Congress's decision to preempt inconsistent state laws and to centralize all enforcement authority in the FDA.

C. "Fraud On The Agency" Claims Interfere Substantially With Federal Government Operations

Federal agencies are charged by statute with faithful execution of federal law — "getting the Government's work done." *Boyle*, 487 U.S. at 505. Permitting private litigants to pursue "fraud on the agency" claims would impede those agencies' ability to carry out their statutory and regulatory duties. Under the Supremacy Clause, States may not "interrupt the acts of the general government" in

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[8] (...continued)
Inc., 59 F.3d 69, 73 (8th Cir. 1995); *Papas* v. *Upjohn Co.*, 985 F.2d 516, 518-519 (11th Cir.), cert. denied, 510 U.S. 913 (1993).

this manner. *Johnson* v. *Maryland*, 254 U.S. 51, 55 (1920); see also *Mayo* v. *United States*, 319 U.S. 441, 445 (1943); *Arizona* v. *California*, 283 U.S. 423, 451 (1931); cf. *Howard* v. *Lyons*, 360 U.S. 593, 597 (1959) (refusing to apply state law that would interfere with the "effective functioning of the Federal Government"); *Hancock* v. *Train*, 426 U.S. 167, 178 (1976) (same).

In some instances, federal safety requirements might reasonably be viewed as "minimum" or "baseline" standards, to be supplemented by additional, more stringent requirements under state law. It is inconceivable, however, that Congress intended federal requirements governing interaction with a federal agency — such as requirements about what information must be submitted in a 510(k) application — to function as a "minimum" to be supplemented by state law. To the contrary, state "supplementation" under these circumstances is a recipe for chaos.

1. If courts applying state law, in the guise of deciding "fraud on the agency" claims, were permitted to interpret federal requirements governing 510(k) submissions, it is inevitable that they would disagree with the FDA and each other about what those requirements entail. Rather than run the risk of liability for "defrauding" the FDA by not submitting information that a court or jury might subsequently find material, manufacturers would seek to comply with the most expansive interpretation.

Thus, manufacturers would inundate the FDA with documentation that the agency itself does not require. Faced with this overload of information, neither the FDA nor consumers would be able to separate wheat from chaff, thus defeating the entire point of the regulatory scheme. And the deluge of paper would not stop with 510(k) clearance, because manufacturers would approach post-clearance reporting obligations[9] with the same incentive to flood the agency with information of uncertain and attenuated relevance.

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[9] *E.g.*, 21 U.S.C. §§ 360i, 360l, 360ll, 360nn; 21 C.F.R. Parts 803, 804, 806, 820 Subpart M, and 821.

Section 510(k) submissions, intended to be a quick and simple means to FDA clearance, would turn into mini-premarket approvals, and the FDA would be drowned in backlogged submissions.[10] The FDA, not state law, should control how much information is provided to the agency.

The threat of state-law liability for "fraud on the FDA" would have negative effects extending beyond this immediate context. As Judge Cowen noted in dissent (Pet. App. 29a-31a), manufacturers might well be reluctant to research and develop new off-label uses, since each such use would be potential evidence of a new "intended use" that, under plaintiffs' theory, should have been disclosed to the FDA and placed on the device's labeling regardless of its safety or efficacy. Even where off-label uses were known, device manufacturers would be loathe to disseminate information about them (by sending reprints of scientific articles in response to physician inquiries or otherwise), for fear that such communications would be taken as evidence of the manufacturer's "true" "intended use" for the device. As a result, physicians would make less informed treatment decisions or simply shy away from off-label uses. This outcome would not only impair the public health — for, as the FDA has recognized, off-label use of devices and drugs can be beneficial to patients, see page 4, *supra* — it would also thrust judges and juries into regulation of medical practice (*i.e.*, off-label use of devices) under the guise of "protecting" the FDA, even though the FDA itself is prohibited from regulating in this area. See 21 U.S.C. § 396; *More Information for Better Patient Care: Hearings on S. 1477 Before the Senate Comm. on Labor and Human Resources*, 104th Cong. 82 (1996) (William B. Schultz,

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[10] This outcome would not only burden the FDA, but also interfere with Congress's clear intent to streamline the regulatory process. In 1997 amendments to the MDA, Congress provided that manufacturers should be permitted to establish "substantial equivalence" under Section 510(k) by the "least burdensome means" possible. See 21 U.S.C. § 360c(i)(1)(D). The FDA has recently implemented regulatory reforms for the specific purpose of expediting clearance decisions. See 65 Fed. Reg. 44540 (2000).

FDA Deputy Comm'r); cf. *Arkansas-Louisiana Gas Co.*, 453 U.S. at 580 (holding that federal law preempts state breach-of-contract claim that "permit[s] a state court to do * * * what the [federal agency] itself may not do").

2. As noted above (at 33), "fraud on the agency" claims require proof of an agency's regulatory requirements, the applicant's failure to satisfy those requirements, and the way in which the agency would have acted differently in the absence of wrongdoing. In every case, the best source of evidence as to these factors — indeed, often the *only* source of credible evidence — would be the agency itself. Accordingly, if these claims were allowed to go forward, private litigants would routinely seek discovery from federal agencies and agency officials to shed light on these crucial issues.

Even if the discovery attempts were unsuccessful,[11] they would drain agency resources. The agency would be obliged to contest discovery requests and to litigate ensuing efforts to obtain compliance. And if the FDA ultimately were not required to provide the critical evidence, the result would be flawed decisionmaking and enormous harm to defendants charged unfairly with having defrauded the agency.

In at least some instances, moreover, discovery attempts would succeed, and federal agencies would become embroiled in private litigation. Government employees would be burdened with having to testify; relevant agency documents would have to be produced; internal deliberations and discussions would have to be revealed;

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[11] The Department of Justice has taken the position that federal employees cannot be forced to testify or produce records in private lawsuits with respect to their official duties. See, *e.g.*, 21 C.F.R. §§ 20.1, 20.2; see generally *United States ex rel. Touhy* v. *Ragen*, 340 U.S. 462 (1951). Some courts have rejected this claim of blanket privilege to resist third-party discovery. *E.g.*, *Exxon Shipping Co.* v. *U.S. Dep't of Interior*, 34 F.3d 774, 778 (9th Cir. 1994); see also 26A C. WRIGHT & K. GRAHAM, FEDERAL PRACTICE & PROCEDURE § 5682, at 206 (1992).

and the agency's ability to obtain expert scientific and technical advice from private advisors would be diminished. See J.A. 31-33. As the Solicitor General observed at the petition stage, "[t]he prospect of such intrusive inquiries" would "pose a significant potential * * * for distorting [the agency's] decision-making processes." U.S. Br. 17.

This case presents a telling example of the way in which federal agencies would be burdened by private litigants pursuing "fraud on the agency" claims. Plaintiffs sought documents from the FDA covering 28 separate topics, including all premarket notifications submitted for spinal use of pedicle screws from January 1, 1993 onward; "[a]ll documents reflecting, relating or referring to any communications regarding each of the relevant premarket notifications and any agency action thereon"; "[a]ll documents reflecting, relating or referring to each 'predicate device' for which substantial equivalence was claimed in each of the relevant premarket notifications"; and "[a]ll documents reflecting, relating or referring to the justification for any agency action taken in response to each of the relevant premarket notifications." J.A. 25-30. Plaintiffs also sought testimony from 14 FDA employees, including five "special" employees who comprised an advisory committee that reviewed pedicle screw systems. J.A. 25-26. The federal government sought a protective order, submitting evidence that special employees would be "hesitant to serve" on advisory panels if they could be subjected to depositions in private lawsuits. J.A. 25, 33, 34-35. Nonetheless, the district court allowed discovery to go forward against all but a single government employee. See *In re Orthopedic Bone Screw Prods. Liab. Litig.*, MDL 1014, slip op. at ¶ 2 (E.D. Pa. Aug. 21, 1995) (PTO 92).

The FDA's regulatory decisions about pedicle screws also fell subject to judicial monitoring and supervision as a result of this litigation. At the request of the district court, the FDA extended the period for filing public comments on the FDA's proposal to reclassify pedicle screws. See *In re Orthopedic Bone Screw Prods. Liab. Litig.*, MDL 1014, slip op. at 1 (E.D. Pa. Jan. 2, 1996) (PTO 188). The FDA was ordered to turn over to plaintiffs its internal

files on an FDA-monitored study on pedicle screw safety, see *In re Orthopedic Screw Prods. Liab. Litig.*, MDL 1014, slip op. at 2 (E.D. Pa. Oct. 16, 1995) (PTO 147), and ultimately to disclose information about the study sufficient to allow identification of participating physicians in breach of the agency's promise of confidentiality. See Pl. Mem. in Support of Pl. Mtn. for Order Requiring Disclosure of Additional Confidential Info. at 4-6, 18-24, Docket No. 1184, *In re Orthopedic Screw Prods. Liab. Litig.*, MDL 1014 (E.D. Pa. filed Dec. 6, 1995).

The interference that this litigation has caused with FDA operations is not aberrational. If state "fraud on the agency" claims were permitted to go forward, their predictable effect would be to swamp federal agencies with information they do not want and have not requested, and generally to interfere with agencies' abilities to carry out their mandated duties. The States have no power, under the Supremacy Clause, to impose these harmful effects on the federal regulatory process.

III. THE COURT SHOULD RECONSIDER ASPECTS OF *MEDTRONIC* THAT ERRONEOUSLY RESTRICT THE SCOPE OF EXPRESS PREEMPTION UNDER THE MDA

As we have explained, plaintiffs' "fraud on the FDA" claim is expressly preempted under Section 360k(a) and this Court's decision in *Medtronic*, as well as impliedly preempted by federal law. But if the Court disagrees with our preemption arguments under current law, it should take this opportunity to revisit and reconsider its conclusion in *Medtronic* that express preemption under Section 360k(a) applies only to "specific" requirements. See page 24, *supra*. With all due respect, the four dissenting Justices in *Medtronic* were correct when they observed that "[t]he statute makes no mention of a requirement of specificity, and there is no sound basis for determining that such a restriction on 'any requirement' exists." 518 U.S. at 512 (opinion of O'Connor, J.).

1. *Stare decisis* "is a principle of policy rather than an inexorable command." *Hohn* v. *United States*, 524 U.S. 236, 251 (1998) (citation and quotation marks omitted). Although the doctrine has more force in statutory cases, this Court has not hesitated to revise its construction of a statute when "a precedent may be a positive detriment to coherence and consistency in the law * * * because of inherent confusion created by an unworkable decision." *Patterson* v. *McLean Credit Union*, 491 U.S. 164, 173 (1989); see also *Monell* v. *New York City Dep't of Soc. Servs.*, 436 U.S. 658, 695 (1978).

Experience has proven this Court's fractured decision in *Medtronic* to be just such a case. As demonstrated in the petition (at 14-16, 19-25), the lower courts have had tremendous difficulty understanding what the decision means and how it should be applied. See also *Wilson* v. *Bradlees of New England, Inc.*, 96 F.3d 552, 559 (1st Cir. 1996) (per Boudin, J.) (this Court's "divisions" in *Medtronic* "make even more general forecasts shaky"), cert. denied, 519 U.S. 1149 (1997). In this respect as well, the *Medtronic* dissenters have turned out to be correct. See 518 U.S. at 509 (opinion of O'Connor, J.) (describing majority's analysis as "bewildering").

The problem lies not just in understanding how the three separate opinions interact to dispose of the issues before the Court (although that has been difficult enough for the lower courts). See Pet. 19-25. It also lies in the hopelessly ambiguous concept of "specificity" itself, which could refer either to the *content* of a requirement (as in Justice Breyer's 2-inch wire, which is "specific" when compared to a more generalized duty to use care in the design of a product) or to a requirement's *applicability* to more than a single device, a single class of devices, or to products in addition to medical devices. As the United States acknowledged at the petition stage (U.S. Br. 10 n.4), even a requirement that is general in content or that applies broadly to products other than medical devices can (and usually does) become "specific" over the course of litigation as the plaintiff develops his precise theory of

liability and as general duties are applied to the individual device at issue.

2. This aspect of *Medtronic* should also be revisited because it rests on an erroneous premise. In adopting the "specificity" requirement as a gloss on Section 360k(a), the majority reasoned that "the FDA has never granted, nor, to the best of our knowledge, even been asked to consider granting, an exemption for a state law of general applicability." 518 U.S. at 499-500. In fact, the FDA has repeatedly treated state requirements that are *not* "specific" — because they are not limited to a single medical device, class of medical devices or even to medical devices in general, or because they are general in content — as eligible for exemption from express preemption. Perhaps the best example of the former is California's Sherman Food, Drug and Cosmetic Law, which contains numerous provisions that are couched in general terms and/or pertain to drugs as well as to medical devices — provisions that the FDA has considered for exemption under Section 360k(b). See 44 Fed. Reg. 19440 (1979); 21 C.F.R. § 808.55(b)(1).[12]

In addition, as noted above (see note 6, *supra*), the FDA has taken the position in regulatory notices, as well as in its brief in *Medtronic* (Nos. 95-754 and 95-886 U.S. Br. 24-25 & nn.19-20), that the federal GMP requirements trigger express preemption and that state GMP regulations are susceptible to express preemption. Indeed, the FDA has indicated that if California — which in passing the Sherman Law "adopt[ed] the FDA GMP regulations as its own" — either "interprets or applies the GMP regulations in

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[12] For example, the FDA has determined that Section 360k(a) preempts a California provision that makes it unlawful "for any person to *advertise* any *drug or* device *represented to have any effect* in any of the following conditions, disorders, or diseases: * * * (m) [d]iseases or disorders of the ear or auditory apparatus, including hearing loss and deafness." 21 CAL. HEALTH & SAFETY CODE § 26463(m) (1984) (emphasis added). According to the FDA, this provision is preempted "to the extent that it applies to hearing aids." 21 C.F.R. § 808.55(b)(2); 45 Fed. Reg. at 67322.

such a way as to make them different from or in addition to the Federal regulations, then the California requirements *will be preempted to that extent*." 45 Fed. Reg. 67321, 67322 (1980) (emphasis added). That plainly indicates that state and federal "requirements" that are expressed generally and that apply to a wide array of medical devices as well as other products fall within the scope of Section 360k(a).

It is no small irony, then, that a majority in *Medtronic* — relying principally on deference to the FDA — held that the federal GMPs do not impose "requirements" that are sufficiently "specific" to trigger express preemption. 518 U.S. at 501. That holding is in fact contrary to the FDA's own longstanding position. For that reason as well, *Medtronic*'s endorsement of the specificity concept should be reconsidered. Deference, in other words, required the opposite result.

In fact, a close examination of the regulatory record indicates that the FDA's "specificity" concept never was intended to be a limitation on the type of *federal* requirements that trigger express preemption under Section 360k(a). Language in the pertinent regulation (21 C.F.R. § 808.1(d)) that was interpreted in *Medtronic* as recognizing a "specificity" limit merely stated that a *counterpart* federal requirement *must be in existence* before state requirements are preempted. See 43 Fed. Reg. 18661, 18662, 18664 (1978); 42 Fed. Reg. 30383, 30383-30384 (1977). In other words, the relevant FDA regulation, read against the backdrop of its regulatory history, was designed to ensure that there would not be a regulatory vacuum immediately after the MDA was passed, in which all state requirements relating to medical devices would be preempted (even before the FDA took any regulatory action to implement the MDA).

3. The final reason why the Court should abandon the "specificity" gloss is that it makes no sense. On the state side, why would Congress have meant to preempt "different" or "additional" state requirements imposed by laws that apply exclusively to medical devices, but to preserve the *very same requirements* if imposed by

laws that apply to other products as well? In either case, the impact on uniformity and the harm to the federal scheme is exactly the same. On the federal side, why would Congress have meant to disable the FDA from issuing a preemptive requirement in regulations that are applicable to all or many devices, but to allow the agency to preempt state law if it imposed exactly the same requirement in a thousand separate regulations, each applicable to a single device? There is simply no reason to attribute to Congress such an absurd design, which would empower States to avoid preemption through skillful drafting and would place formalistic restrictions on the FDA's power to issue preemptive requirements. And if "specificity" relates to the *content* (as opposed to the *applicability*) of state and federal requirements covered by Section 360k(a), how would a court determine when a requirement is "specific" enough to come within Section 360k(a)?

Not surprisingly, this Court has repeatedly rejected invitations to read similar limitations into other express preemption provisions. Illustrative is *Morales* v. *Trans World Airlines, Inc.*, 504 U.S. 374 (1992), which involved a provision of the Airline Deregulation Act of 1978 ("ADA") that "pre-empts the States from 'enact[ing] or enforc[ing] any law, rule, regulation, standard or other provision * * * relating to rates, routes, or services of any air carrier.'" *Id.* at 383 (quoting 49 U.S.C. App. § 1305(a)(1)). The Court categorically rejected the argument that "only state laws specifically addressed to the airline industry are pre-empted, whereas the ADA imposes no constraints on laws of general applicability." *Id.* at 386. [13] Such an interpretation, this Court noted,

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[13] Accord *Pilot Life Ins. Co.* v. *Dedeaux*, 481 U.S. 41, 47-48 (1987) (ERISA preemption is not limited to state measures targeting ERISA plans but also includes more general common law tort and contract causes of action); *San Diego Bldg. Trades Council* v. *Garmon*, 359 U.S. 236, 244 & n.3 (1959) ("Nor has it mattered [in cases involving NLRA preemption] whether the States have acted through laws of broad general application rather than laws specifically directed

(continued...)

would create "an *utterly irrational loophole*." *Ibid.* (emphasis added). That criticism applies with equal force to the interpretation of Section 360k(a). The Court should take this opportunity to eliminate this "utterly irrational loophole" from the law of express preemption under the MDA.

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted.

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[13] (...continued)
towards the governance of industrial relations.")

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IN THE

Supreme Court of the United States

THE BUCKMAN COMPANY,

Petitioner,

v.

PLAINTIFFS' LEGAL COMMITTEE,

Respondent.

ON WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

BRIEF FOR RESPONDENT

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TABLE OF CITED AUTHORITIES

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Cases:

Albertson v. Richardson-Merrell, Inc., 441 So. 2d 1146 (Fla. App. 4th Dist. 1983), *pet. for review denied*, 451 So. 2d 850 (Fla. 1984) 22

Alberty Food Products v. United States, 194 F.2d 463 (9th Cir. 1952) 4

Allen v. McCurry, 449 U.S. 90 (1980) 24, 31

Alyeska Pipeline Service Co. v. Wilderness Society, 421 U.S. 240 (1975) 49

Arkansas La. Gas Co. v. Hall, 453 U.S. 571 (1981) 43, 44

Askew v. American Waterways Operators, Inc., 411 U.S. 325 (1973) 30, 40

Boyle v. United Technologies Corp., 487 U.S. 500 (1988) 30

Bradley v. United States, 264 F. 79 (5th Cir. 1920) ... 5

California v. ARC America Corp., 490 U.S. 93 (1989) 32

California v. FERC, 495 U.S. 490 (1990) 24

Cited Authorities

Page

California v. Sierra Club, 451 U.S. 287 (1981) ... 25

California v. Zook, 336 U.S. 725 (1949) 31, 32

Cannon v. University of Chicago, 441 U.S. 677 (1979) 25

Chicago and N.W. Transp. Co. v. Kalo Brick & Tile Co., 450 U.S. 311 (1981) 44

Church of Scientology of California v. Richardson 4

Cipollone v. Liggett Group, Inc., 505 U.S. 504 (1992) 34, 37

Cort v. Ash, 422 U.S. 66 (1975) 25

CSX Transp., Inc. v. Easterwood, 507 U.S. 658 (1993) 26, 31, 32, 37, 40

Davis v. Dep't of Labor and Industries of Wash., 317 U.S. 249 (1942) 43

DeCanas v. Bica, 424 U.S. 351 (1976) 31, 40

English v. General Elec. Co., 496 U.S. 72 (1990) ... 29, 32

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Evraets v. Intermedics Intraocular, Inc., 29 Cal. App. 4th 779, 34 Cal. Rptr. 2d 852 (1994) 22

Fogal v. Steinfeld, 620 N.Y.S.2d 875 (N.Y. Sup. 1994) 40

Freightliner Corp. v. Myrick, 514 U.S. 280 (1995) .. 29, 37

Gade v. Nat'l Solid Wastes Management Assn., 505 U.S. 88 (1992) 37

Geier v. American Honda Motor Co., 120 S. Ct. 1913 (2000) 29, 31, 49

Haberman v. Washington Public Power Supply System, 744 P.2d 1032 (Wash. 1987), *amended*, 750 P.2d 254, *app. dism'd*, 488 U.S. 805 (1988) 22

Handy v. Beck, 581 P.2d 68 (Or. 1978) 22

Hawkins v. Upjohn Co., 890 F. Supp. 609 (E.D. Tex. 1994) 22

Hillsborough Cty., Fla. v. Automated Medical Labs., 471 U.S. 707 (1985) 34

Hines v. Davidowitz, 312 U.S. 52 (1941) 29

Howlett v. Rose, 496 U.S. 356 (1990) 31

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Humana, Inc. v. Forsyth, 525 U.S. 299 (1999) 38

Idaho v. Coeur d'Alene Tribe of Idaho, 521 U.S. 261 (1997) 24, 31

Ingalls Shipbuilding, Inc. v. Director, Office of Workers' Compensation Programs, U.S. Dept. of Labor, 519 U.S. 248 (1997) 46, 47

In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prod. Liab. Litig., MDL 1203, PTO 1461 (Oct. 12, 2000) 46

In re Orthopedic Bone Screws Prods. Liab. Litig., 1995 WL 925680 (Jan. 31, 1995) 12

In re Orthopedic Bone Screws Prod. Liab. Litig., PTO 51 (Jun. 1, 1995) 12

In re Orthopedic Bone Screws Prod. Liab. Litig., 1995 WL 925670, PTO 87 (Aug. 10, 1995) 12

In re Orthopedic Bone Screws Prod. Liab. Litig., PTO 92 (Aug. 18, 1995) 12

In re Orthopedic Bone Screws Prod. Liab. Litig., 176 F.R.D. 158 (E.D. Pa. 1997) 13

Johnson v. Fankell, 520 U.S. 911 (1997) 24, 31

Kordel v. United States, 335 U.S. 345 (1948) 5

Cited Authorities

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Learjet Corp. v. Spenlinhauer, 901 F.2d 198 (1st Cir. 1990)	22
Lowe v. General Motors Corp., 624 F.2d 1373 (5th Cir. 1980)	25
Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996)	*passim*
Merrell Dow Pharmaceuticals, Inc. v. Thompson, 478 U.S. 804 (1986)	25
Michael v. Shiley, 46 F.3d 1316 (3d Cir.), *cert. denied*, 516 U.S. 815 (1995)	22
Miree v. DeKalb County, Ga., 433 U.S. 25 (1977)	30
Nature Food Centres, Inc. v. United States, 310 F.2d 67 (1st Cir. 1962), *cert. denied*, 371 U.S. 968 (1963)	5
Ostano Commerzanstalt v. Telewide Systems, Inc., 794 F.2d 763 (2d Cir. 1986)	22
Pratico v. Portland Terminal Co., 783 F.2d 255 (1st Cir. 1985)	25, 26
Redland Soccer Club, Inc. v. Dep't of Army of U.S., 55 F.3d 827 (3d Cir. 1995), *cert. denied*, 516 U.S. 1071 (1996)	46

Cited Authorities

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Retail Clerks Intern. Ass'n Local 1625, AFL-CIO v. Schermerhorn, 375 U.S. 96 (1963)	36
San Diego Building Trades Council v. Garmon, 359 U.S. 236 (1959)	32
Shaw v. Delta Air Lines, Inc., 463 U.S. 85 (1983)	26, 31, 32
Silkwood v. Kerr-McGee Corp., 464 U.S. 238 (1984)	*passim*
Stanton by Brooks v. Astra Pharmaceuticals Products, Inc., 718 F.2d 553 (3d Cir. 1983)	23
Trans Penn Wax Corp. v. McCandless, 50 F.3d 217 (3d Cir. 1995)	38
United States v. An Article ... Consisting of 216 Cartoned Bottles, 409 F.2d 734 (2d Cir. 1969)	4
United States v. Articles of Drug for Veterinary Use, 50 F.3d 497 (8th Cir. 1995)	5
United States v. Ballistrea, 101 F.3d 827 (2d Cir. 1996), *cert. denied*, 520 U.S. 1150 (1997)	5
United States v. Evers, 453 F. Supp. 1141 (M.D. Ala. 1978), *aff'd*, 643 F.2d 1043 (5th Cir. 1981)	6

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United States v. Hohensee, 243 F.2d 367 (3d Cir.), *cert. denied*, 353 U.S. 976 (1957)	4, 5
United States v. One Unlabeled Unit ..., 885 F. Supp. 1025, 1028 (N.D. Ohio 1995)	5
United States v. Rodgers, 466 U.S. 475 (1984)	47
United States v. Sene X Eleemosynary Corp., 479 F. Supp. 970 (S.D. Fla. 1979)	6
United States v. Storage Spaces Designated Nos. 8 & 49, 777 F.2d 1363 (9th Cir. 1985)	6
United States v. 250 Jars, etc., 344 F.2d 288 (6th Cir. 1965)	4
United States v. Utah Constr. and Mining Co., 384 U.S. 394 (1966)	43
United States ex rel. Touhy v. Ragen, 340 U.S. 462 (1951)	45
Washington Legal Foundation v. Friedman, 13 F. Supp. 2d 51 (D.D.C. 1998), *amended*, 36 F. Supp. 2d 16 (D.D.C. 1999)	2
Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609 (1973)	1
Woodward v. Dietrich, 548 A.2d 301 (Pa. Super. 1988)	22

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Statutes:	
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18 U.S.C. § 1001	5, 20
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21 U.S.C. § 321(g)	4
21 U.S.C. § 321(h)	4
21 U.S.C. § 321(m)	5
21 U.S.C. § 331-335	29, 38
21 U.S.C. § 331(q)(2)	6, 20
21 U.S.C. § 336	29
21 U.S.C. § 337	18
21 U.S.C. § 337(a)	29
21 U.S.C. § 355	2
21 U.S.C. § 360, *et seq.*	2
21 U.S.C. § 360c	2

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21 U.S.C. § 360c(a)(1)(C)	3
21 U.S.C. § 360c(f)	3
21 U.S.C. §§ 360c(f)(1)	20
21 U.S.C. § 360c(f)(1)(A)	3
21 U.S.C. § 360c(i)(1)(A)	4, 20, 27
21 U.S.C. § 360c(i)(1)(E)(i)	28
21 U.S.C. § 360d(b)	11
21 U.S.C. § 360e	3
21 U.S.C. § 360e(a)	3
21 U.S.C. § 360e(b)(1)(A)	3
21 U.S.C. § 360e(b)(1)(B)	3
21 U.S.C. § 360e(c)	3
21 U.S.C. § 360e(d)(2)(A)	3
21 U.S.C. § 360(h)	29, 38
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28 U.S.C. § 1927	49
Arizona Rev. Stat. Ann. § 12-701	42
Mich. Comp. Laws Ann. § 600.2946(5)	42
N.J. Stat. Ann. § 2A:58C-5	42
Ohio Rev. Code Ann. § 2307.80c	42
Or. Rev. Stat. § 30.927	42
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FED. R. CIV. P. 11	38, 49
FED. R. CIV. P. 23(b)(1)(B)	13
FED. R. CIV. P. 54(b)	14
Pa. R. CIV. P. 1019(b)	38
Other Authorities:	
Adler, R. & Mann, R., *Preemption and Medical Devices: The Courts Run Amok*, 59 Mo. L. Rev. 895 (1994)	25

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American Law Institute, *Enterprise Responsibility for Personal Injury*, Reporters' Study (Vol. II) (Weiler, ed. 1991) 41

Comments by Plaintiffs' Legal Committee in *In re Orthopedic Bone Screw Prods. Liab. Litig.*, MDL 1014, Concerning Proposed Rule Making ("PLC Comments"), FDA Dkt. No. 95N-0176 (Mar. 1, 1996) 9

Garber, S., *Product Liability and the Economics of Pharmaceuticals and Medical Devices*, 127 (Rand 1993) 39

General Accounting Office, *Medical Devices — FDA's 510(k) Operations Could be Improved*, GAO/PEMD-88-14 (Aug. 1988) 40

Green, M.D., *Statutory Compliance and Tort Liability: Examining the Strongest Case*, 30 *U. MICH. J. LAW REFORM* 461 (1997) 39, 40, 41

Hayes, T.A., *Drug Labeling and Promotion: Evolution and Application of Regulatory Policy*, 51 FOOD & DRUG L.J. 57 (1996) 1

Hearings before a Subcom. of the Comm. on Commerce of the U.S. Senate on S. 1944, 73d CONG., 2d Sess. 400 (1933) 25

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HHS/IG, Report, *Internal Control Weaknesses in the Food and Drug Administration's Medical Device 510(k) Review Process*, A-15-89-00065 (Jul. 1990) 40

H.R. 956 (Common Sense Product Liability and Legal Reform Act of 1995), 104th CONG., 1st SESS., § 201(f) (reprinted and debated in 141 Cong. Rec. H2941-H2948) (Mar. 9, 1995) (passed, 141 CONG. REC. H3027) (Mar. 10, 1995) 42

H.R. 2015 (Balanced Budget Act of 1997), 105th CONG., 1st SESS., § 4812(d)(B)(i) (set forth in 143 CONG. REG. H4416-01 at H4476) (Jun. 25, 1997) 42

H.R. 2425 (Medicare Preservation Act), 104th CONG., 1st SESS., § 15312 (set forth in 141 CONG. REC. H10147) (Oct. 17, 1995) 42

H.R. 2723 (BiPartisan Consensus Managed Care Improvement Act of 1999), 106th CONG., 1st SESS., § 412(b)(4) (set forth in 145 Cong. Rec. H9523-01 at H9554 (Oct. 7, 1999)) 42

H.R. REP. NO. 94-853 (1976) 2, 6

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H.R. Report by the Subcomm. on Oversight and Investigations of the Comm. on Energy and Commerce, *Less Than the Sum of its Parts — Reforms Needed in the Organization, Management and Resources of the Food and Drug Administration's Center for Devices and Radiological Health*, GPO PRINT NO. 103-N (May 1993) 40

Inspector General of the Department of Health and Human Services (HHS/IG), Report, *Investigative Devices: Four Case Studies*, OEI-05-94-00100 (Apr. 1995) 40

W. Page Keeton, *Prosser and Keeton on the Law of Torts*, § 36 220 (5th ed. 1984) 23

Merrill, R.A., *Compensation for Prescription Drug Injuries* 59 *VA.L.REV.* 1 (1973) 39

Nightingale, S.L. *Unlabeled Use of Approved Drugs*, DRUG INFORMATION JOURNAL, 26:141-47 (1992) 48

Rodgers, A.E., *FDA Pedicle Screw Cohort Study: Audit Findings*, FDA Dkt. No. 95N-0176 (Jul. 30, 1996) 11

S. REP. No. 93-670 (1974) 2

S. REP. No. 94-33 (1976) 2

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21 C.F.R. § 20.1 ..... 12, 45, 46

21 C.F.R. § 201.128 5

21 C.F.R. § 801.1, *et seq.* 20

21 C.F.R. § 801.4 ..... 4, 5, 27

21 C.F.R. § 807.81, *et seq.* 3, 20

21 C.F.R. § 807.87(e) 4, 5, 27

21 C.F.R. § 807.87(h) 5

21 C.F.R. § 807.87(k) 20

21 C.F.R. § 807.100(a)(1) 6

21 C.F.R. § 807.100(a)(2) 6

21 C.F.R. § 807.100(b) 20

21 C.F.R. § 808.1(d) 19

21 C.F.R. § 812, *et seq.* 3, 48

21 C.F.R. § 814.1(c)(1) 3

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21 C.F.R. § 820.1, *et seq.*	20
21 C.F.R. § 888.3070	11, 48
21 C.F.R. § 890.3150	4
57 Fed. Reg. 18062	39
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63 Fed. Reg. 40026	10
63 Fed. Reg. 40027	11
63 Fed. Reg. 40030	10
63 Fed. Reg. 40035	11
63 Fed. Reg. 40038	6
121 CONG. REC. S. 6140 (Apr. 17, 1975)	24
132 CONG. REC. S12071-01 (Sept. 8, 1986)	42
RESTATEMENT (SECOND) OF TORTS § 285(b), cmt. c	23
RESTATEMENT (SECOND) OF TORTS § 286, cmt. c	23
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RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 4	23, 41
RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6, cmt. b (1998)	41
S. 640 (Product Liability Fairness Act), 102d CONG., 2d SESS., § 303(c)(1)(B) (set forth in 138 CONG. REC. S13115-02 at S13117) (Sept. 9, 1992) (explained in S. REP. 102-215 (1991))	42
S. 687 (Product Liability Fairness Act), 103d CONG., 2d SESS., § 203(b)(2) (set forth in 139 CONG. REC. S4112-03 at S4149) (Mar. 31, 1993) (proposed amendments set forth in 140 CONG. REC. S7790-01 (Jun. 28, 1994))	42
S. 2760 (Product Liability Reform Act), 99th CONG., 2d SESS., § 303(c)(1)(B) (set forth in 132 CONG. REC. S12071-01) (Sept. 8, 1986) (amending original markup draft of S. 1999)	42
S. REP. NO. 105-43 (1997)	28

Cited Authorities

	Page
U.S. Mem. of Law in Opp. to PMC's Motion to Compel, Dkt. No. 201402, MDL 1203 (E.D. Pa.)	46
Vanden Brink, K.D. & Edmonson, A.S., 2 *Campbell's Operative Orthopaedics*, 1992-97 (6th ed. 1980)	7
Weeks, E., *Is It Worth the Trouble? The Policy On Dissemination of Information on Off-Label Drug Use Under the Food and Drug Administration Modernization Act of 1997*, 54 FOOD & DRUG L.J. 645 (1999)	48

STATEMENT

In *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), this Court unanimously determined that the Medical Device Amendments to the Food, Drug and Cosmetic Act do not expressly foreclose state power to afford a private damage remedy for violations of the Act. This case presents the question of whether Congress nonetheless implicitly intended to preempt such claims.

A. THE REGULATORY BACKGROUND

Historically, the safety of drugs and medical devices has been a central concern of the common law. *See* Hayes, T.A., *Drug Labeling and Promotion: Evolution and Application of Regulatory Policy*, 51 FOOD & DRUG L.J. 57, 60 (1996). The damage remedy provided by the common law, however, did not prove to be a sufficient deterrent to assure that these products safely achieved the therapeutic uses claimed for them. Congress enacted the Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 301, *et seq.*, to address this threat. *Medtronic*, 518 U.S. at 475-78; *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 617-20 (1973).

The central tenet of the FDCA is that clinical trials, rather than the "beliefs" of physicians, are necessary to properly judge the safety and effectiveness of drug products. As this Court observed in *Weinberger*, 412 U.S. at 619:

> [The] strict and demanding standards [of the FDCA], barring anecdotal evidence indicating that doctors "believe" in the efficacy of a drug, are amply justified by the legislative history. The hearings underlying the 1962 Act [regarding the regulation of drugs] show a marked concern that impressions or beliefs of physicians, no matter how fervently held, are treacherous.[1]

[1] The danger of using drugs or devices based on clinical theory or the anecdotal experience of physicians was vividly illustrated in the 1980s when physicians began to prescribe the drug Flecainide, off label, to treat arrhythmias. The drug proved effective in controlling irregular (Cont'd)

Accordingly, the law provides that a new drug may not be introduced into commerce unless the FDA makes a determination based on the outcome of clinical trials, that there is a reasonable assurance that the drug is actually safe and effective in treating the particular maladies for which the drug is offered to physicians and their patients. 21 U.S.C. § 355.

The law, as originally enacted, required premarket approval for drugs but did not authorize control over the marketing of new medical devices. *See* S. REP. No. 93-670 at 1-2 (1974); H.R. REP. No. 94-853 at 6 (1976). This omission proved to be a mistake. For example, in 1970, A.H. Robbins began marketing the Dalkon Shield as a safe and effective contraceptive device without performing clinical trials to support these claims. *Medtronic*, 518 U.S. at 476. The widespread use of this untested device resulted in a significant number of pregnancies, serious infections, and deaths. *Id.*; *see also* H.R. REP. No. 94-853 at 8. This experience, along with a general recognition that existing law was inadequate to protect consumers from "increasingly complex devices which pose serious risk if inadequately tested or improperly designed or used," led Congress to enact the Medical Device Amendments ("MDA") to the FDCA, 21 U.S.C. § 360, *et seq.* *See* S. Rep. No. 94-33 (1976); *Medtronic*, 518 U.S. at 475-76.

Under the Medical Device Amendments, the FDA is required to place medical devices into one of three regulatory categories that are subject to three corresponding levels of regulatory control. *See* 21 U.S.C. § 360c. Class III devices are those which "present[ ] a potential unreasonable risk of illness or injury." These devices are subject to premarket approval

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heartbeats. However, when clinical trials were finally conducted with respect to this "off-label treatment," it appeared that those who took the drug had a 2½-fold increase in mortality and that 3,000 to 10,000 patients per year had died as a consequence of this "treatment." *See Washington Legal Foundation v. Friedman*, 13 F. Supp. 2d 51, 56 (D.D.C. 1998), *amended*, 36 F. Supp. 2d 16 (D.D.C. 1999).

("PMA") by the FDA. *See* 21 U.S.C. §§ 360c(a)(1)(C) & 360e. The FDA may not grant a premarket approval unless it determines that there is a "reasonable assurance" that the device is safe and effective based on an evaluation of data from controlled clinical trials. *See* 21 U.S.C. §§ 360e(c), 360e(d)(2)(A) & 360j(g); 21 C.F.R. §§ 812 & 814.20; *Medtronic*, 518 U.S. at 477. The premarket approval process "is a rigorous one" to which agency officials typically devote an average of 1,200 hours. *Medtronic*, 518 U.S. at 477.

All Class III devices, including those in commerce at the time the MDA was enacted, are subject to the premarket approval process. 21 U.S.C. §§ 360c(a)(1)(C) & 360e(a). New, post-enactment devices are automatically treated as Class III devices that can not be marketed without a PMA. 21 U.S.C. § 360c(f). Existing medical devices, however, could not be withdrawn from the market while the FDA completed the classification and PMA review processes for such devices. *Medtronic*, 518 U.S. at 477-78. Therefore, a "grandfathering" provision was included in the legislation. *Id.* It provides that all devices which were in commerce as of the date of the enactment could remain on the market pending the eventual completion of the classification and PMA processes for such devices. 21 U.S.C. § 360e(b)(1)(A); 21 C.F.R. § 814.1(c)(1). In order to avoid monopolies in grandfathered devices, Congress enacted an exception to the rule prohibiting the sale of new Class III devices. This exception permits the marketing of a new, post-enactment device if the FDA finds that it is "substantially equivalent" to a "predicate device." A predicate device is one that was lawfully on the market before the enactment of the MDA in 1976. 21 U.S.C. §§ 360c(f)(1)(A) & 360e(b)(1)(B); *Medtronic*, 518 U.S. at 478. "Substantial equivalence" is claimed and either accepted or rejected through a "premarket notification" submitted under § 510(k) of the FDCA, 21 U.S.C. § 360(k). This provision requires a first-time marketer to submit a notification to the FDA advising the agency of its intent to market a new medical device. *See* 21 U.S.C. § 360(k); 21 C.F.R. § 807.81, *et seq.* A device is not "substantially equivalent" unless

"the device has the same intended use as the predicate device." 21 U.S.C. § 360c(i)(1)(A).

"Intended use" is at the heart of the FDCA regulatory scheme. *See* 21 U.S.C. §§ 321(g) & (h). It determines whether a product is a drug or device, the character of the product, the regulatory requirements to which it is subject, and the extent of those requirements. Thus, for example, a screw that is intended for use in constructing a car is not a medical device subject to regulation under the FDCA. The same screw, if intended for use in constructing crutches, would be a Class I medical device subject to minimal regulation. 21 C.F.R. § 890.3150. If that screw were intended for use in the human spine, it would be a Class III medical device subject to premarket approval. J.A. 105.

"Intended use" refers to the manner in which those responsible for the distribution of a drug or device characterize the product in the marketplace as demonstrated by "labeling claims, advertising matter, or oral or written statements by such persons" and other "circumstances surrounding the distribution of the article."[2]

[2] *See, e.g.*, 21 C.F.R. §§ 801.4, 814.20(b)(3)(ii) & 807.87(e); 63 Fed. Reg. 40025, 40038 (Jul. 27, 1998) ("the term 'intended use' is broadly defined and encompasses the manner in which a company characterizes its product in the marketplace."); 59 Fed. Reg. at 59821-25; *Church of Scientology of California v. Richardson*, 437 F.2d 214, 217 (9th Cir. 1971) (skin galvanometer used in religious practices of Scientology deemed "device" based on literature that "contain[ed] diagnostic and therapeutic claims"); *United States v. An Article ... Consisting of 216 Cartoned Bottles*, 409 F.2d 734, 739, 742 (2d Cir. 1969) (a cosmetic, such as facial lotion, can be a drug regardless of its actual physical effects, when marketed as a "face lift without surgery"); *United States v. 250 Jars, etc.*, 344 F.2d 288, 289 (6th Cir. 1965) (honey classified as a drug when it is sold for therapeutic purposes); *United States v. Hohensee*, 243 F.2d 367, 370 (3d Cir.), *cert. denied*, 353 U.S. 976 (1957) (ordinary food product, such as peppermint tea leaves, may be drug based on claims); *Alberty Food Products v. United States*, 194 F.2d 463, 464 (9th Cir. 1952) (intended use judged (Cont'd)

Given the primacy of intended use in making the substantial equivalence determination, FDA's regulations provide that a premarket notification must include "[p]roposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use." *See* 21 C.F.R. § 807.87(e). Congruent with the concept of intended use, "labels" and "labeling" are not limited to the package insert that physically accompanies an article, but also include all other written and graphic materials which are separately distributed as part of an integrated series of transactions designed to result in the sale or distribution of the product including, for example, manuals, brochures, catalogues, booklets, and video tapes.[3] In addition, a 510(k) submission must include "any additional information" requested by the FDA "that is necessary . . . to make a finding as to" substantial equivalence. *See* 21 C.F.R. § 807.87(h).

The statements made in a 510(k) notification must be truthful. Federal law generally outlaws fraudulent submissions to federal agencies. 18 U.S.C. § 1001. And, the FDCA specifically prohibits "[w]ith respect to any device, the submission of any report . . . that is false or misleading in any

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objectively by characterization in the market); *Bradley v. United States*, 264 F. 79, 82 (5th Cir. 1920) (mineral water a drug where label claimed that product cured or alleviated certain diseases); *United States v. One Unlabeled Unit . . .*, 885 F. Supp. 1025, 1028 (N.D. Ohio 1995) (vinyl-covered bed with audio speakers deemed "device" where brochure claimed that bed "improve[d] circulation and balance," "reduce[d] the need for insulin," and "reduce[d] cholesterol").

[3] *See, e.g.*, 21 U.S.C. § 321(m); 21 C.F.R. §§ 201.128 & 801.4; *Kordel v. United States*, 335 U.S. 345, 348-50 (1948) ("literature"); *United States v. Ballistrea*, 101 F.3d 827, 830 (2d Cir. 1996), *cert. denied*, 520 U.S. 1150 (1997) ("literature and audiotapes"); *United States v. Articles of Drug for Veterinary Use*, 50 F.3d 497, 500 (8th Cir. 1995) ("written literature consisting of a brochure, two University and Field Trial Results booklets, a pamphlet, and an advertisement"); *Nature Food Centres, Inc. v. United States*, 310 F.2d 67, 69 (1st Cir. 1962), *cert. denied*, 371 U.S. 968 (1963) (lectures and Class Notes on Health and Nutrition); *Hohensee*, 243 F.2d at 369-70 ("leaflets and advertising copy," "lecture," and "printed materials").

material respect." 21 U.S.C. § 331(q)(2). The FDA is peculiarly dependent on compliance with this fundamental obligation of candor in the 510(k) process, because this process is an abbreviated one, consuming only 20 hours of agency time, on average. *Medtronic*, 518 U.S. at 479. Accordingly, the FDA's practice has been to make determinations of substantial equivalence based on the assumption that the applicant has provided it with correct information concerning the intended use of the device and without making any independent determination as to the accuracy of those representations. *See* Pet'r. Br., 21; J.A. 85-87.

The FDA's action on a 510(k) notification does not amount to an approval. Rather, the agency simply determines whether the device is substantially equivalent to a legally-marketed predicate device. *See* 21 C.F.R. §§ 807.100(a)(1) & (2). If the product is found to be substantially equivalent, the device may be introduced into commerce for the intended use described in the 510(k) notification. However, because different intended uses for the same physical article give rise to different and distinct devices, an article which is determined to be substantially equivalent for one intended use may not be labeled, marketed, or promoted for a different use.[4]

B. Buckman's Fraudulent Conduct

This case involves medical devices intended for use in spinal fusion surgery. *See* J.A. 6. During such surgery, bone is harvested

[4] *See, e.g.*, 63 Fed. Reg. at 40038 ("If . . . statements or materials promote a use [for a device] that has not been approved by the agency, the device is misbranded [and] . . . [t]he device is also adulterated"); 59 Fed. Reg. at 59821 ("The listing of unapproved uses in the labeling or advertising of an approved device results in an adulterated medical device under section 501(f)(1)(B) of the act"); H.R. Rep. No. 94-853 at 14-15 ("It is the Committee's intention that each use may . . . be treated as constituting a different device for purposes of classification and other regulation"); *United States v. Storage Spaces Designated Nos. 8 & 49*, 777 F.2d 1363, 1366-67 (9th Cir. 1985); *United States v. Sene X Eleemosynary Corp.*, 479 F. Supp. 970, 978 (S.D. Fla. 1979); *United States v. Evers*, 453 F. Supp. 1141, 1149 (M.D. Ala. 1978), *aff'd*, 643 F.2d 1043 (5th Cir. 1981); J.A. 92.

from the patient's hip or a cadaver and applied to the bones in the spine to cause them to fuse together. *Id.* Although spinal fusion can be used in treating fractures, it is typically used to treat a variety of other conditions such as a "slipped disc," curvature of the spine, and spinal tumors. *See* Vanden Brink, K.D. & Edmonson, A.S., 2 *Campbell's Operative Orthopaedics*, 1992-97 (6th ed. 1980). Sometimes spine surgeons augment the fusion by attaching instrumentation to the spine to stabilize it while the fusion process takes place. *Id.* at 1997-2002. Prior to 1984, however, no doctor in the United States ever used a fixation device that was attached to the spine by screws inserted into the spinal pedicles, the thin bony archways that surround the spinal cord and nerves. J.A. 10.

In 1983, Arthur Steffee, M.D., formed AcroMed Corporation to "[m]anufacture and sell . . . spinal implants and instrumentation." J.A. 39. The company, through Steffee, developed and applied for a patent on a device which came to be known as the Variable Screw Placement ("VSP") Spinal Plate Fixation System. J.A. 42. As described in the patent documents, the device was specifically designed for use as an adjunct to spinal fusion surgery, and consisted of plates which were to be affixed to the spine with pedicle screws. J.A. 42-44; *see also* J.A. 88-89.

In 1984, AcroMed retained petitioner, The Buckman Company ("Buckman"), to assist it in obtaining 510(k) "clearance" for the VSP device. On September 4, 1984, and again on September 20, 1985, Buckman filed premarket notifications for the "VSP Spinal Fixation Plating System." J.A. 45-46, 93-94 & 100-01. These notifications truthfully represented that the device was intended for use in spinal fusion surgery. *Id.* On both occasions, the FDA informed Buckman that it had determined that the device was not substantially equivalent to any legally-marketed predicate device. J.A. 101-06. Accordingly, the agency also advised Buckman that the device was a Class III device that could not be commercially distributed without receiving premarket approval.

Id. The agency explained that these determinations were based on the fact that Buckman had not demonstrated that there was "a pre-amendment device . . . with a design substantially equivalent to the VSP Spine Plate System" and on the fact that the device "pose[d] potential risks not exhibited by other spinal fixation systems," including "greater chance of neurological deficit due to imprecise screw placement or the event of screw failure" and "soft tissue damage or inadequate fusion due to bending or fracture of device components." J.A. 105.

On December 12, 1985, a meeting took place among representatives of Buckman, AcroMed, and the FDA. J.A. 94. At that meeting, AcroMed asked whether it could label and sell the components of the VSP system for use in repairing fractures in the long bones of the arms and legs. J.A. 95. The FDA responded that in order for AcroMed to do so "it would have to submit separate 510 (k) applications for these purposes and that the FDA would evaluate those applications individually." J.A. 95.

In late December, 1985, Buckman submitted two new premarket notifications for what it described as "Nested Bone Plates" and "Cancellous Bone Screws." J.A. 46-57. These plates and screws were, in reality, the components of the VSP system. J.A. 95, 107-08; Pet. App. 5a. Buckman's December, 1985, premarket notifications omitted all reference to use of the device components in the spine and claimed that plates and screws were substantially equivalent to pre-amendment Class II devices intended for use in the repair of arm and leg fractures. J.A. 46-57. The notifications did not include any proposed labeling or promotional materials which indicated that the plates and screws would be marketed as components of a spinal fixation construct. *Id.* The FDA then sought clarification from Buckman concerning the intended use of the plates and screws. *See* J.A. 95 & 107. In a letter dated January 10, 1986, Buckman responded to this inquiry. J.A. 57-58. In that letter, Buckman affirmatively represented to the FDA that these device components were "intended for use in appropriate fractures of

long bones of both the upper and lower extremity." J.A. 58 & 96.

Shortly thereafter, the FDA determined that AcroMed's plates and screws were substantially equivalent to pre-enactment devices for the repair of long bone fractures — the intended use claimed by Buckman. J.A. 59-62 & 96.

The representations made by Buckman to the FDA were false and misleading. J.A. 86, 96-97. Indeed, within days of Buckman's representations, AcroMed's president admitted that the characterization of the plates and screws as a long bone fixation device was "a labeling slight-of-hand" that "in no way changes the intended use of the plates and screws." J.A. 65. AcroMed's vice president and chief counsel admitted under oath that the only purpose of AcroMed's plates and screws was for spinal fixation. J.A. 108; *see also* J.A. 42 (VSP System "is a spine device"). AcroMed's vice president of operations admitted to FDA enforcement officials that the plates and screws were "always intended for use in the spine and [were] never distributed to parties who were not known to have the skills and training to implant [them] in the spine." J.A. 69. Dr. Steffee himself admitted under oath that the device was properly characterized as a spinal plate and screw rather than a long bone fixation device. J.A. 42; *see also* J.A. 88-89. In fact, it was physically impossible to use the plates and screws in long bone repair. Comments by Plaintiffs' Legal Committee in *In re Orthopedic Bone Screw Prods. Liab. Litig.*, MDL 1014, Concerning Proposed Rule Making ("PLC Comments"), FDA Dkt. No. 95N-0176, Tab 278 at 7-8 (Mar. 1, 1996).

In the marketplace, AcroMed consistently characterized its plates and screws as a spinal fixation device and marketed the device exclusively for that purpose. J.A. 12, 75-79, 97, 124-26. Contemporaneous with 510(k) clearance, AcroMed formed a medical advisory panel which consisted of a cadré of key spine surgeons who agreed to serve in exchange for lucrative options to purchase AcroMed stock. J.A. 97. The members of the medical advisory panel agreed to promote the use of AcroMed's plates and screws in spinal surgery and trained surgeons for

that use. PLC Comments, 42. AcroMed would not ship its plates and screws unless it was demonstrated that they were going to be used by a spine surgeon who had been trained by one of the members of the AcroMed medical advisory panel to implant the device in the spine. J.A. 67, 75. Accordingly, AcroMed sponsored and conducted training sessions for hundreds of spine surgeons in which the members of its medical advisory panel provided instruction in the spinal application of AcroMed's plates and screws. *See* J.A. 75 & 76. In addition, AcroMed furnished physicians with video tapes (J.A. 73, 78), a "technique manual" (J.A. 80-83 & 97), product catalogues (J.A. 97 & 113), price lists (J.A. 109-13), and patient booklets (*e.g.*, J.A. 115-18), all of which characterized the AcroMed plates and screws exclusively as a spinal fixation construct. None of these materials mentioned use of the plates and screws in repairing long bone fractures. Indeed, it appears that there was not a single instance where AcroMed or Buckman ever characterized the plates and screws as a long bone fixation device.

An FDA investigation into the conduct of AcroMed and Buckman concluded as of October 7, 1991 that the agency had been defrauded as to the intended use of the AcroMed plates and screws. J.A. 124. However, by the time the government reached this conclusion an entire "Pedicle Screw" industry had emerged. This created a regulatory conundrum for the spinal implant industry, for orthopaedic surgeons, and for the FDA. As stated in a memorandum summarizing a series of meetings among those interests in the winter of 1993, "[t]he FDA, industry, and orthopaedics are all caught between a rock and a hard place; [and] need to find a way out." PLC Comments, 76 & Tab 90.

This "way out" was provided by the so-called "Cohort Study." The Cohort Study was sponsored by an association of "spinal implant manufacturers," including AcroMed. 63 Fed. Reg. at 40030. The stated purpose of the study was to gather "scientific" evidence to support reclassification of pedicle screw devices by the FDA so that they could be sold without premarket approval. *Id.* at 40026.

The FDA audited the results of the Cohort Study. According to a July 30, 1996 memorandum from the FDA's Division of Bioresearch Monitoring (BIMO), "the audit findings seem to reveal a poorly executed study," and the study data were "unreliable in evaluating the treatment under consideration." *See* Rodgers, A.E., *FDA Pedicle Screw Cohort Study: Audit Findings*, FDA Dkt. No. 95N-0176 (Jul. 30, 1996). BIMO also recommended a criminal investigation of the study. *Id.* However, FDA officials admitted that in their approach to the downclassification of pedicle screw fixation devices, "neither the scientific soundness nor the results of the retrospective [Cohort Study] process [were] of great importance." PLC Comments, 98 & Tab 166. Accordingly, the scientifically-infirm Cohort Study became the basis for a regulation reclassifying pedicle screw fixation devices, which was promulgated on July 27, 1998. *See* 21 C.F.R. § 888.3070. Significantly, this regulation retained Class III status for pedicle screw fixation devices when used for all but seven specific indications. With respect to these seven indications, the devices were placed in regulatory Class II subject to four special controls which were (a) "[c]ompliance with materials standards"; (b) "compliance with mechanical testing standards of performance"; (c) "compliance with biocompatibility standards"; and (d) "adherence to labeling requirements." 63 Fed. Reg. at 40027. None of these special controls were in effect prior to the promulgation of the regulation.[5] While the FDA commentary accompanying the regulation stated that the "FDA does not believe that pedicle screw spinal systems present a substantial deception" (63 Fed. Reg. at 40035), the agency made it clear that it had made no determination concerning whether any person's prior

[5] The MDA provides that performance standards of the type required in the reclassification regulation must be promulgated by regulation. *See* 21 U.S.C. § 360d(b). Such performance standards have not yet been promulgated. In addition, the labeling requirements set forth in the reclassification regulation were not imposed formally by regulation or informally in connection with the 510(k) clearance of AcroMed's plates and screws.

conduct in introducing pedicle screw fixation devices into the marketplace was fraudulent or otherwise illegal and that the reclassification regulation should not be understood to validate prior unlawful conduct. *See* U.S. Br., Pet. Stage, 14.

C. The Proceedings Below

Many individuals were injured as a result of having AcroMed's hardware attached to their spines in proximity to the delicate nerves emanating from their spinal cords. The resulting lawsuits were largely filed in or removed to federal district courts and transferred by the Judicial Panel on Multidistrict Litigation to the Eastern District of Pennsylvania for coordinated pretrial proceedings (Transfer Order of JPMDL, Aug. 4, 1994), where the court appointed a Plaintiffs' Legal Committee ("PLC") to coordinate the litigation on behalf of the plaintiffs. *Orthopedic Bone Screws*, 1995 WL 925680 (Jan. 31, 1995).

In the early, prediscovery stages of the MDL proceedings, the court entered PTO 12 in which it ruled that to the extent plaintiffs sought to recover damages suffered by virtue of misrepresentations to the FDA, their claims were foreclosed by the express preemption section of the MDA, 21 U.S.C. § 360k. Pet. App., 48a-50a. Thus, there was no discovery directed to the FDA concerning the issue of Buckman's fraud on the agency.[6]

Approximately one year after the transferee court dismissed plaintiffs' fraud claims, this Court issued its decision in *Medtronic*. Contemporaneous with *Medtronic*, some of the MDL plaintiffs filed pleadings in which they named defendants

[6] Substantially later in the MDL proceedings, the district court permitted plaintiffs to direct discovery to the FDA in order to meet defenses which were affirmatively based on FDA actions during the period from 1993 to 1998. *See Orthopedic Bone Screws*, PTO 51 (Jun. 1, 1995); *Orthopedic Bone Screws*, 1995 WL 925670, PTO 87 (Aug. 10, 1995); *Orthopedic Bone Screws*, PTO 92 (Aug. 18, 1995); J.A. 36-37. However, consistent with the FDA's "housekeeping regulation," 21 C.F.R. § 20.1, plaintiffs were not permitted to depose full-time employees of the FDA. *Id.*

in addition to those who actually sold the products that injured them. *See, e.g.*, J.A. 5. Buckman was named as one of the non-seller defendants in these so called "Omni Complaints." *E.g.*, J.A. 5. The complaints against Buckman alleged that Buckman and AcroMed contrived and implemented a strategy to fraudulently obtain 510(k) clearance of AcroMed's plates and screws for use in repairing arm and leg fractures and to then market the device components solely for use in spinal fusion procedures. J.A. 13-21. Plaintiffs alleged that as a result of this scheme, AcroMed's pedicle screw devices unlawfully reached the market where they were implanted within the plaintiffs' spines, causing them to suffer the very same injuries that the FDA cited as device risks when it refused marketing clearance in the first instance. J.A. 21.

In October, 1996, the MDL parties submitted a stipulation to the district court in which they agreed that the question of whether plaintiffs' fraud claims were preempted in light of *Medtronic* would be presented to the district court in the form of a motion by AcroMed to reaffirm PTO 12, which had dismissed plaintiffs' fraud-on-the-FDA claims at the outset of the MDL litigation. *See* 3d Cir. Appendix in App. No. 97-1783, A40. While that motion was pending, the PLC reached a limited-fund class action settlement with AcroMed pursuant to Fed. R. Civ. P. 23(b)(1)(B). *Orthopedic Bone Screws*, 176 F.R.D. 158 (E.D. Pa. 1997).

With AcroMed's departure from the litigation, another manufacturer was treated as a moving party on the motion to reaffirm the district court's prior ruling concerning preemption of plaintiff's "fraud-on-the-FDA claims." Pet. App. 33a. On March 28, 1997, the district court granted this motion. In doing so, it explicitly recognized that plaintiffs' fraud claims were not preempted in light of *Medtronic*. Pet. App. 40a. However, the district court reasoned that allowing a fraud-on-the-FDA claim would create a private right of action for violation of the FDCA and that, "in view of the FDA's exclusive prosecutorial discretion . . . any grant of an implied private right of action would be contrary to the letter and spirit of the statute."

Pet. App. 37a. Based on this ruling, the district court granted a separate Rule 12 motion to dismiss, which was filed by Buckman. Pet. App. 45a. The dismissal of this claim against Buckman was certified as a final order subject to immediate appellate review under FED. R. CIV. P. 54(b). Pet. App. 54a-56a.

In a two-to-one decision, the Court of Appeals reversed, holding that no principle of federal law prevented plaintiffs from proceeding with state-law claims that were predicated upon Buckman's alleged misrepresentations to the FDA. Pet. App. 1a. The Court of Appeals' reasoning was straightforward.

First, the Court of Appeals held that "[a]bsent preemption by federal law . . . a district court . . . cannot decline to enforce liability imposed by the relevant state common law." Pet. App. 14a. Second, it recognized that preemption is a matter of legislative intent and "where Congress has expressed itself on preemption in a statute, Congress' [preemptive] intent primarily is discerned from the language of the pre-emption statute and the 'statutory framework' surrounding it." Pet. App. 15a. Third, the court recognized that the MDA contains an express preemption provision, 21 U.S.C. § 360k, which was definitively construed by this Court in *Medtronic*. As the Court of Appeals read that decision, the MDA only preempts state law to the extent that there is a federal requirement "with respect to" the specific device that caused the injuries for which plaintiffs seek to recover under state law. Pet. App. 18a. Because there were no device-specific regulatory requirements relating to AcroMed's plates and screws, the court found, there was no preempting federal requirement to displace the application of state law. Pet. App. 13a. Fourth, the Court of Appeals observed that § 360k was unanimously construed by this Court in *Medtronic* as manifesting a Congressional intent to allow states to provide "a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements." Pet. App. 16a. Because plaintiffs' claims were based on a common-law duty to refrain from making misrepresentations, which is identical to the duty imposed by federal law, the court concluded that "the state common law

relied upon does not impose any obligation on Buckman inconsistent with federal law" and was not preempted. Pet. App. 13a. Finally, while the Court of Appeals did not "rule out the possibility that there may be some areas of preemption outside the scope of § 360k based on clear and direct conflicts between the requirements of state law and those of the FDCA," it found "no inconsistency between the FDA having the exclusive prerogative of bringing actions to enforce the FDCA and preserving the right of people in the plaintiffs' position to bring common law fraudulent misrepresentation claims." Pet. App. 18a. Thus, implied preemption was not appropriate.

SUMMARY OF THE ARGUMENT

In *Medtronic*, this Court unanimously ruled that the express preemption language of the MDA did not foreclose state power to provide a private damage remedy for violation of the requirements imposed by federal medical device law. The Court reached this conclusion notwithstanding its explicit recognition that the FDCA sets forth a comprehensive regulatory scheme for enforcing the requirements of the MDA, which does not include a private, federal right to damage relief. In the present matter, the plaintiffs seek damages under conventional concepts of state tort law for personal injuries they received as a result of the petitioner's violation of federal requirements governing truthful disclosure of information in the 510(k) process. Under *Medtronic*, the claim is not subject to express preemption.

In the context of examining Congress' expressed intent regarding MDA preemption, *Medtronic* rejected the principal arguments made to support implied "conflict" preemption here. Rejection of these arguments is no less compelling in the context of implied preemption. First, there is no reason to believe that Congress intended a broader preemption with respect to state-law claims based on MDA violations than that which it expressed in section 360k. Second, under the Court's jurisprudence, permitting a private damage remedy to redress the wholly private interest in freedom from bodily harm, does not create a preempting conflict with the federal remedial scheme, even where the plaintiff seeks damages as a result of a

violation of federal law. Third, it is inconsistent with basic notions of federalism to imply preemption based on the fact that a state tribunal may be called upon to interpret and apply federal regulatory law in a private damage action. State tribunals are presumptively competent to do so. Fourth, allowing a non-federal remedy for violation of a federal requirement provides incentives for compliance with federal mandates and, thus, generally advances rather than conflicts with federal interests. Finally, as demonstrated by the *Silkwood* decision, the Court has been loathe to invoke implied preemption to preclude the award of damages even where, unlike the present matter, the substantive area at issue is one that is subject to exclusive federal regulatory control.

ARGUMENT

I. Respondent's Fraud Claims Are Not Expressly Preempted

A.

The Medical Device Amendments contain a specific provision expressing Congress' intent with respect to the preemptive reach of the legislation, 21 U.S.C. § 360k. It provides that "no State . . . may establish or continue in effect with respect to a device . . . any requirement — (1) which is different from, or in addition to, any requirement applicable under this chapter to the device. . . ." This express provision was definitively construed by the Court in *Medtronic*.

In *Medtronic*, the plaintiffs sought to recover damages for an injury allegedly caused by a Class III medical device that reached the market through the 510(k) substantial equivalence process. 518 U.S. at 480-83. Recovery was premised on multiple theories including design defect, "violat[ion of] FDA regulations," labeling inadequacy and manufacturing deficiencies. *Id.* at 481, 495. The manufacturer of the device, Medtronic, advanced numerous arguments in support of its contention that these claims were preempted. Each argument was rejected.

First, Medtronic made an argument similar to that advanced by petitioner here: "that any common-law cause of action is a

'requirement' which alters incentives and imposes duties 'different from, or in addition to,' the generic federal standards that the FDA has promulgated in response to mandates under the MDA" and that, therefore, "the plain language of the statute pre-empts any and all common-law claims brought by an injured plaintiff against a manufacturer of medical devices." *Id.* at 486.

The Court unanimously rejected this argument, holding that the language of the statute did not justify such a sweeping preemptive effect. If Congress intended such an effect, the Court reasoned, it could have achieved that result by precluding "any 'remedy' under state law relating to medical devices" rather than limiting preemption to state requirements. *Id.* at 487. Moreover, the legislative history did not justify the conclusion that the breadth of the federal regulatory scheme displaced the ability of state law to provide a damage remedy to persons harmed by medical devices. The legislators who enacted the MDA were "acutely aware of ongoing product liability litigation" involving medical devices, yet there was absolutely nothing in the legislative history "suggesting that any proponent of the legislation intended a sweeping pre-emption of traditional common-law remedies against manufacturers and distributors of defective devices." *Id.* at 491. Moreover, the legislation was intended to provide greater protections with respect to the dangers posed by unsafe medical devices than those that existed prior to enactment of the law. *Id.* at 487. Given that "there is no explicit private cause of action against manufacturers contained in the MDA, and no suggestion that the Act created an implied private right of action," the Court found, "Medtronic's construction of § 360k would therefore have the perverse effect of granting complete immunity . . . to an entire industry that, in the judgment of Congress, needed more stringent regulation in order to 'provide for the safety and effectiveness of medical devices' . . . ." *Id.* at 487. Harking to the principle established by this Court's *Silkwood* opinion, the Court refused to accept that Congress intended such an outcome. *Id.* at 487, *citing Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984).

Next, the Court unanimously concluded that an essential prerequisite to statutory pre-emption under section 360k was the existence of a federal requirement having the same subject matter as (and thus subject to potential conflict with) the state "requirements" which formed the basis for the plaintiff's tort claim. *Id.* at 492-94; *see also id.* at 513 (O'Connor, J., concurring in part). While "the FDA may well examine 510(k) applications for Class III devices (as it examines the entire medical device industry) with a concern for the safety and effectiveness of the device," *id.* at 493, the 510(k) substantial equivalency process "places no 'requirements' on a device," *id.* at 513 (O'Connor, J.). Therefore, all of the members of the Court agreed that a 510(k) clearance determination by the FDA does not preempt design defect claims. *Id.* at 493-94 & 513.

The Court's decision was unanimous in one other respect. The complaint at issue in *Medtronic* "include[d] claims that Medtronic has, to the extent that they exist, violated FDA regulations." *Id.* at 495. In asserting that these claims were preempted, Medtronic made exactly the same argument that petitioner makes here. Like Buckman, Medtronic argued that the FDCA's lack of an "express private right of action" and 21 U.S.C. § 337 signified Congressional intent to bar state-law claims based upon federal duties. *See* Br. for Cross-Respondent Medtronic in *Medtronic*, Nos. 95-754 & 95-886 at 43 (U.S., Mar. 29, 1996). As Medtronic put it "Congress's omission of a private right of action reflects an intent to reserve enforcement of federal requirements exclusively to the federal government." *Id.*

In a ruling which could not be any more direct (and any more devastating to Buckman's position here), the Court rejected Medtronic's argument. Under a section of the opinion entitled "Identity of Requirements," the Court held that damage claims based on FDCA violations "can be maintained without being pre-empted by § 360k." *Medtronic*, 518 U.S. at 495. Because the MDA preempts only state-law requirements that are "different from or in addition to" federal requirements and because allowing a remedy for unlawful conduct does not

amount to the imposition of a "requirement," the MDA, does not preempt state-law claims to the extent that they seek damages for alleged violations of federal requirements. "Nothing in § 360k denies [the state] the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements." *Id.* In other words, a claim of negligence *per se* or some other state-law claim premised on a violation of federal law is not barred by the FDCA. Indeed, rather than being inconsistent with the FDCA, a state-law damages remedy to enforce MDA standards "merely provides another reason for manufacturers to comply with identical existing 'requirements' under federal law." *Id.* Justice O'Connor summarized this point as follows:

> To be sure, the threat of a damages remedy will give manufacturers an additional cause to comply [with federal law], but the requirements imposed on them under state and federal law do not differ. [The MDA] does not preclude States from imposing different or additional remedies, but only different or additional requirements.

Id. at 513.

Finally, the Court grappled with the proper construction of section 360k insofar as it limited preemption to state requirements that are "different from or in addition to" a federal requirement "applicable to the device." A majority of the Court accepted the interpretation contained in the FDA's preemption regulation, 21 C.F.R. § 808.1(d), ruling that a federal requirement is not potentially preemptive unless it is "specific" to a "particular device." *Medtronic*, 518 U.S. at 500. The FDA's Good Manufacturing Practices and labeling regulations are not device-specific and thus do not preempt common-law labeling or manufacturing defect claims. *Id.* at 497-500. While those federal regulations "reflect important but entirely generic concerns about device regulation," they do not evince "the sort of concerns regarding a specific device or field of device regulation that the statute or regulations were designed to protect

from potentially contradictory state requirements." *Id.* at 501 (plurality); *see also id.* at 507 (Breyer, J., concurring).

Under *Medtronic*, section 360k does not preempt the claims made by plaintiffs here.

To begin with, during the time at issue, there were no device-specific regulations that related to pedicle screw fixation devices, to orthopedic instrumentation or to any other matter germane to the plaintiffs' deceit claims. Certainly, the agency's generic 510(k) regulations and the statutes governing truthful disclosures to the FDA applied to Buckman's conduct, but these requirements are no more specific than the Good Manufacturing Practices and labeling regulations, which *Medtronic* judged insufficient to displace potentially conflicting duties under state tort law. Indeed, they are less so. *Compare* 21 C.F.R. § 801.1, *et seq.* & § 820.1, *et seq.*, *with* 21 C.F.R. § 807.81, *et seq.*

Moreover, the agency's application of its generic 510(k) regulations to the AcroMed devices does not give rise to potentially preemptive, device-specific mandates. Just as there is nothing in the statute or regulations regarding the 510(k) notification process which requires the FDA to come to a specific conclusion regarding device safety in terms of the design, labeling or manufacture of devices, there is nothing which requires the agency to evaluate the truthfulness of a 510(k) submission with respect to intended use or any other matter. *See* 21 U.S.C. §§ 360c(f)(1) & 360c(i)(1)(A); 21 C.F.R. § 807.100(b). In fact, the FDA does not do so as a matter of routine practice. *See* Pet'r. Br., 21. Therefore, an FDA determination of substantial equivalence pursuant to a 510(k) notification no more represents a preempting "requirement" with respect to the representations made in such a notification than it represented a preempting requirement with regard to the design, labeling or manufacture of the device in *Medtronic*.

Finally, federal statutory law expressly prohibits the making of fraudulent statements to the FDA. *See* 21 U.S.C. § 331(q)(2); 18 U.S.C. § 1001; 21 C.F.R. § 807.87(k). Here, the basis for plaintiffs' fraud claim is that Buckman deceived the FDA by making false statements to the agency concerning an issue of

paramount regulatory concern — the intended use of AcroMed orthopedic plates and screws. Thus, plaintiffs seek recovery for Buckman's "violation of federal requirements." If *Medtronic* was clear about anything, it was clear that such claims are not preempted by section 360k.

B.

Petitioner seeks to avoid these conclusions on four grounds. First, it argues that the holding in *Medtronic* only applies in actions where the theory of recovery is a "traditional" one. Second, Buckman claims that the ruling in *Medtronic* is limited to those cases that do not require a judge or jury to make any determination concerning the existence and breach of a duty under federal medical device law. Third, it argues, *sotto voce*, for reconsideration of the decision in *Medtronic* on the ground that recognition of a state-law right to recover damages for violation of FDCA requirements is at odds with Congress' determination not to recognize a federal private cause of action. Fourth, it claims that its conduct did not actually amount to a violation of federal requirements.

1. With respect to the first argument, demanding a "traditional" theory of recovery as a condition to avoiding preemption, Buckman parses the dialect of *Medtronic* in a way which neither the Court's language nor its reasoning justify. The focus of the Court's preemption analysis in the "Identity of Requirements" section of the decision was not on the heritage of state-law theories of liability which allow recovery for conduct that violates a federal statutory requirement. Indeed, given the range of potential causes of action which are recognized by state law, the variety of elements that must be proven to establish the breach of duty component for each such cause of action and the inherently plastic nature of the common-law process, it probably would be impossible for Congress to establish meaningful rules of preemption based on a determination of whether and to what extent a state-law theory of recovery was "traditional." Rather, the Court's focus in *Medtronic* was on the statutory language which allowed the assertion of a state-law claim for "violation of federal

requirements" or "to enforce an FDCA requirement," because section 360k "does not preclude States from imposing different or additional remedies, but only different or additional requirements." *Medtronic*, 518 U.S. at 495-97 & 513.

Moreover, the theory of recovery advanced by the plaintiffs here is, in fact, squarely within the common law tradition. A longstanding principle of common law holds that where one sustains injuries as a result of another's justifiable reliance on a fraudulent misrepresentation, he or she may recover damages for such injuries from the maker of the misrepresentation.[7] In a special application of this general rule, the law holds that where a statute or regulation requires information to be furnished, filed, or recorded with a government agency for the protection of a particular class of persons, one who makes a fraudulent misrepresentation in meeting such requirements is liable for the harm caused by his or her deceptive conduct.[8]

In addition, one of the most fundamental and long-standing tenets of our tort jurisprudence is that liability is established "per se" if an actor's conduct violates a statute, ordinance or regulation which is intended to protect individuals in the position of the plaintiff from harm caused by the kind of conduct at issue, regardless of whether there is an express or implied

[7] *See, e.g., Michael v. Shiley*, 46 F.3d 1316, 1334-35 (3d Cir.), *cert. denied*, 516 U.S. 815 (1995); *Ostano Commerzanstalt v. Telewide Systems, Inc.*, 794 F.2d 763, 765-66 (2d Cir. 1986); *Haberman v. Washington Public Power Supply System*, 744 P.2d 1032 (Wash. 1987), *amended*, 750 P.2d 254, *app. dism'd*, 488 U.S. 805 (1988); *Evraets v. Intermedics Intraocular, Inc.*, 29 Cal. App. 4th 779, 791 n.5, 34 Cal. Rptr. 2d 852, 858 n.5 (1994); *Woodward v. Dietrich*, 548 A.2d 301 (Pa. Super. 1988); *Albertson v. Richardson-Merrell, Inc.*, 441 So. 2d 1146 (Fla. App. 4th Dist. 1983), *pet. for review denied*, 451 So. 2d 850 (Fla. 1984); RESTATEMENT (SECOND) OF TORTS §§ 531, 533, 536 & 557A.

[8] *See, e.g.*, RESTATEMENT (SECOND) OF TORTS §§ 536 & 557A; *Learjet Corp. v. Spenlinhauer*, 901 F.2d 198, 199-201 (1st Cir. 1990); *Hawkins v. Upjohn Co.*, 890 F. Supp. 609, 611-12 (E.D. Tex. 1994); *Handy v. Beck*, 581 P.2d 68, 73-74 (Or. 1978).

statutory right of action for violation of the governmental requirement.[9]

The 510(k) notification procedure is an integral part of a regulatory scheme which is designed to protect members of the unsuspecting public from being exposed to drugs and devices that are "harmful *in potentia*" because their safety and efficacy has not been demonstrated in well-controlled scientific investigations. *See* pp. 1-4, *supra*. While 510(k) clearance does not itself adjudicate safety in device-specific terms, it is, in effect, the legal checkpoint to determine whether a device is a new Class III device that presents potential unreasonable risks of illness or injury and therefore must be evaluated through clinical trials and the PMA process before being allowed into the marketplace. *Id.* Thus, it is clear that the 510(k) notification procedure directly implicates public safety concerns. Accordingly, misrepresentations made in that process affect safety and are actionable under the traditional tort doctrines described above.

Thus, even though preemption does not depend on a determination of the extent to which plaintiff's cause of action is a "traditional one," it is clear that the present claim is squarely within the common law pedigree.

2. Buckman's second argument is equally unavailing. Under *Medtronic*, preemption turns, in part, on whether plaintiffs' state-law claim is premised on "common law duties [which] parallel federal requirements" or "seeks to enforce an FDCA requirement" through a damage action. Therefore, in order to determine if the claims are preempted, a judge will necessarily have to determine in the first instance what the federal law "requires" and a jury will, *per force*, have to determine whether those requirements have been violated. In other words, under *Medtronic*, § 360k necessarily contemplates that judges and juries will construe and apply

[9] *See, e.g.*, RESTATEMENT (SECOND) OF TORTS §§ 285(b), cmt. c & 286, cmt. c; RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 4; W. Page Keeton, *Prosser and Keeton on the Law of Torts*, § 36 at 220 (5th ed. 1984) (citing cases); *Stanton by Brooks v. Astra Pharmaceuticals Products, Inc.*, 718 F.2d 553, 563-65 (3d Cir. 1983).

federal requirements as the permitted foundation for state-law damage actions qualified to avoid preemption. This is consistent with the historic principle of federalism, which accepts "the constitutional obligation of the state courts to uphold federal law" and affirms emphatically this Court's "confidence in their ability to do so." *Idaho v. Coeur d'Alene Tribe of Idaho*, 521 U.S. 261, 275 (1997); *Allen v. McCurry*, 449 U.S. 90, 105 (1980). "When pre-emption of state law is at issue, [courts] must respect the 'principles [that] are fundamental to a system of federalism in which the state courts share responsibility for the application and enforcement of federal law.' " *Johnson v. Fankell*, 520 U.S. 911, 922 (1997).

3. Buckman's third argument comes to this Court with little grace. Overruling *Medtronic* is inconsistent with the "cardinal and guiding principle" of *stare decisis* which has "special force in the area of statutory interpretation." *California v. FERC*, 495 U.S. 490, 499 (1990).[10] It is particularly inappropriate considering the fact that the Court was unanimous on the "Identity of Requirements" issue.

On the merits, Buckman is simply wrong in suggesting that there is an inconsistency between refusing to recognize an implied private federal right to recover damages for conduct that violates federal law and permitting states to recognize a right to a damage remedy for such conduct.

First, from the vantage point of Congressional intent, the legislative history of the FDCA demonstrates that there is no

[10] In addition to its *de facto* suggestion that the Court overrule the "Identity of Requirements" holding in *Medtronic*, petitioner explicitly suggests that the Court should also overrule *Medtronic* to the extent that it requires a device-specific federal regulation as a predicate to express preemption under § 360k. That would be inappropriate because of the principle of *stare decisis*, cited above, because the rationale for requiring device specificity expressed by the majority in *Medtronic* is sound and because the MDA was "written so that the benefit of the doubt is always given to the consumer [because] after all, it is the consumer who pays with his health and his life for device malfunctions." 121 CONG. REC. S. 6140 (Apr. 17, 1975).

conflict between recognizing state-law damage claims for violation of FDCA requirements and Congress' omission to provide a private right of recovery under the Act. *Medtronic*, 518 U.S. at 487-91. Indeed, in 1938, when Congress was considering the legislation that ultimately became the FDCA, it specifically rejected a proposal to include a private right of action for damages caused by faulty or unsafe products regulated under the Act, on the ground that such a right of action already existed under state common law. *See, e.g.*, Hearings before a Subcom. of the Comm. on Commerce of the U.S. Senate on S. 1944, 73d CONG., 2d Sess. 400, 403 (1933); *see also* Adler, R. & Mann, R., *Preemption and Medical Devices: The Courts Run Amok*, 59 Mo. L. Rev. 895, 924 & n.130 (1994) ("Congress rejected a provision in a draft of the original FD&C Act providing a federal cause of action for damages because 'a common law right of action (already) exists'").

Moreover, the federal "implication doctrine" does not justify Buckman's position. That doctrine determines the circumstances under which federal law will recognize a private right of relief enforceable in a federal court as a federal cause of action where a federal statute imposes substantive obligations, but is silent regarding the availability of individual relief. *See, e.g., California v. Sierra Club*, 451 U.S. 287, 293 (1981); *Cannon v. University of Chicago*, 441 U.S. 677, 687-709 (1979); *Cort v. Ash*, 422 U.S. 66, 78 (1975). By its own terms, it is not concerned with the separate question of foreclosing relief under state law. *Id*; *Merrell Dow Pharmaceuticals, Inc. v. Thompson*, 478 U.S. 804, 805, 810 & 814 (1986). Indeed, the federal implication doctrine expressly defers to the viability of state law by providing that courts should be reluctant to "imply" the existence of a federal remedy for conduct in violation of a federal statute where the "cause of action is a subject traditionally relegated to state law." *See Merrell Dow*, 478 U.S. at 811, *citing Sierra Club*, 451 U.S. at 293 and *Cort*, 422 U.S. at 78.

Further, under the common law, a court does not "imply" a remedy for violation of a statute. *E.g., Lowe v. General Motors Corp.*, 624 F.2d 1373, 1379 (5th Cir. 1980); *Pratico v. Portland*

Terminal Co., 783 F.2d 255, 265 (1st Cir. 1985). In the case of liability *per se*, it merely uses a federal requirement to define an existing duty under state law when state law already recognizes a private right to relief. *Id.* In the case of a misrepresentation to a regulatory body, it simply applies state law concerning actionable misrepresentation where a federal regulatory body, by circumstance, is the causal intermediary between the deceptive conduct of the defendant and the harm suffered by plaintiff. *See* fns. 7, 8 & 9, and accompanying text, *supra*.

Finally, because states are free to create a cause of action with respect to virtually any matter relating to public health and safety, they should certainly be free, under basic notions of state-federal comity, to use federal law as a standard of conduct and impose liability for damages caused by a breach of that standard in the absence of a clear and unequivocal expression by Congress of a contrary intent. *See, e.g., Medtronic*, 518 U.S. at 495-97 & 513; *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 668 (1993); *Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85, 101-02 (1983).

4. Petitioner's final argument is that plaintiffs' common-law theory imposes a requirement that is different from the applicable federal requirement because, under federal law, "intended use" supposedly refers to the "objective" use set forth in the proposed product labeling submitted in the 510(k) notification, while plaintiffs' common-law theory purportedly equates intended use to a manufacturer's subjectively-desired off-label uses. In effect, petitioner contends that for purposes of a 510(k) notification, "intended use" is whatever the manufacturer says it is and is not legally susceptible to misrepresentation as a matter of law. These contentions misconstrue the applicable federal standards and the allegations in the complaints here.

If Congress expected that the FDA was to make substantial equivalence determinations based solely on whether the proposed labeling in a 510(k) notification described a type of device that was on the market prior to 1976, it would have been

simple enough to say that. However, the statute says that a device is not substantially equivalent to a pre-enactment device unless it actually has the same intended use as that predicate device. *See* 21 U.S.C. § 360c(i)(1)(A). "Intended use" is a well-established statutory concept that refers to the manner in which a device will actually be characterized by sellers in the marketplace — not only in the "package insert" that physically accompanies the device, but also through other materials such as catalogs, manuals, brochures, price lists, and other circumstances and expressions surrounding the distribution of the product. *See* fns. 2 & 3 and accompanying text, *supra*.

The agency's 510(k) regulations also make this explicit. These regulations do not simply direct a 510(k) applicant to submit the proposed "package insert" for a new device. Rather, the applicant is required to submit "[p]roposed labels, labeling, and advertisements sufficient to describe the device [and] its intended use." 21 C.F.R. § 807.87(e). In this regard, "labeling" is a well-understood statutory concept which includes all written and graphic materials that are to be employed in bringing the product to physicians and their patients. *See* fn. 3, *supra*.

Because "intended use" describes the manner in which a device is characterized in the market by those responsible for its sale, it is frequently said that the statutory phrase refers to the seller's "objective" intent. *See* 21 C.F.R. § 801.4. This objective approach to the definition of "intended use" and the related definition of "labeling" was developed by the law to effectuate the legislative intent of protecting consumers from the dangers of medical products which are physically labeled for one purpose but actually marketed for more dangerous uses. *See* fns. 2 & 3, *supra*. Therefore, the characterization of "intended use" as "objective" should not be twisted to negate the application of the concept in the all important premarket situation. In this context, "intended use" necessarily refers to the manner in which the proposed seller intends to characterize the device. The concept remains objective because it refers to the actual, objective marketing of the device rather than the seller's hopes or expectations as to how the device will be used.

The recent amendments to the MDA, which purportedly codify the FDA's prior practice of accepting a 510(k) applicant's representations concerning intended use, do not alter this conclusion. *See* 21 U.S.C. § 360c(i)(1)(E)(i); *see also* S. REP. No. 105-43 at 27 (1997). As the government itself says, while these amendments may relieve the FDA of an administrative burden, they do not relieve the applicant of the obligation to accurately inform the FDA of the actual use intended for the product. *See* U.S. Br., 15, n.2. Indeed, if the rule were otherwise, the MDA would have virtually no effect. Through the simple expedient of submitting a proposed label reflecting a pretextual use which matched a pre-enactment use, a new device could reach the market without regulatory constraint. *See* U.S. Br., 15.

This does not mean that one cannot request 510(k) clearance for a device with the hope or even the expectation that it will be used "off label," nor does it mean that a 510(k) clearance must list every potential use of a device. However, it does mean that if someone requests marketing clearance under section 510(k), they must, at a minimum, truthfully describe the manner in which they expect that the device will be characterized by its sellers and distributors — the "objective" intended use of the product.

It is this simple regulatory requirement which lies at the heart of the plaintiffs' claims. Plaintiffs do not allege that Buckman merely submitted a 510(k) notification to the FDA with the subjective hope, knowledge or expectation that the device at issue would be used "off label" for spinal fixation and failed to disclose this to the FDA. Rather, plaintiffs have alleged and proven that Buckman affirmatively told the FDA that the device at issue was intended for use in repairing arm and leg fractures when it had no expectation that the device would actually be described that way by anyone and specifically intended that the device would be characterized in the market and used solely as a spinal fixation device. Whether judged objectively, subjectively, or any other way, Buckman flat out lied to the FDA. It is hard to imagine a violation of federal law

which is any plainer than this. And it is hard to imagine a situation in which *Medtronic* applies any more forcefully to permit states to provide a private damage remedy.

II. RESPONDENT'S FRAUD CLAIM IS NOT SUBJECT TO IMPLIED PREEMPTION

A.

Preemption does not flow exclusively from explicit statements of Congressional intent. The petition here raises a question of implied "obstacle" preemption — does the award of damages under state law to victims injured as a consequence of a fraudulent submissions to the FDA "stand[ ] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress"? *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941). *See also Freightliner Corp. v. Myrick*, 514 U.S. 280, 281 (1995); *English v. General Elec. Co.*, 496 U.S. 72, 79 (1990).

Several important principles serve as guideposts in making this determination.

1. The preemptive consequences of the distinction between "requirements" and "remedies" articulated in *Medtronic* with respect to express preemption is equally significant in the area of implied preemption. While the Court has not been reticent to find implied preemption to the extent that state-law claims are based on liability requirements which would impose different or additional substantive duties under state-law than those which exist under federal law, *Geier v. American Honda Motor Co.*, 120 S. Ct. 1913, 1925 (2000), the Court has refrained from finding implied preemption of private remedies for breach of substantive duties which do not differ from federal requirements. This is true for a number of reasons.

To begin with, the federal government's regulatory interests are usually vindicated through a fairly prolix amalgam of remedies such as warnings, fines, penalties, injunctions, cease-and-desist orders and the like, which the federal regulators are given discretion to invoke as they believe necessary to advance the statutory goals entrusted to them. *See, e.g.*, 21 U.S.C. §§ 331-335c, 336, 337(a), 360(h). Allowing private litigants to

employ a remedy not entrusted to the quiver of regulatory enforcement mechanisms in order to vindicate private interests is inherently *de hors* the regulatory scheme. In and of itself, it does not impliedly "conflict" with federal law. Where "only the rights of private litigants are at issue," providing a remedy for the violation of a federal requirement will, by definition, affect only the litigants and will not have the kind of direct impact on the United States, which preemption is designed to protect from undue incursion. *Miree v. DeKalb County, Ga.*, 433 U.S. 25, 30-32 (1977); *Askew v. American Waterways Operators, Inc.*, 411 U.S. 325, 336 (1973).

In *Miree*, for example, private parties sued a municipality for breach of an agreement between the municipality and the Federal Aviation Administration on the theory that the private parties were third-party beneficiaries of the federal contract. The contract required the municipality to "restrict the use of land adjacent to or near the airport to activities compatible with normal aircraft operations, including landings and takeoffs." *Miree*, 433 U.S. at 25. The municipality allegedly operated a garbage dump adjacent to an airport, in violation of the FAA contract, which attracted a swarm of birds that caused a plane crash. Although federal common law undoubtedly would have controlled in any suit by or against the federal government to enforce the contract, and although "[t]he operations of the United States in connection with FAA grants . . . are undoubtedly of considerable magnitude," and although "the United States has a substantial interest in regulating aircraft travel and promoting air travel safety," the state-law claim was not preempted. *Id.* at 30-31. Preemption was inappropriate because "only the rights of private litigants are at issue here," because the claim against the municipality "will have no direct effect upon the United States," *id.* at 29-30, and because the suit did not seek to "impose upon the person contracting with the Government a duty contrary to the duty imposed by the Government contract." *Boyle v. United Technologies Corp.*, 487 U.S. 500, 508-09 (1988) (explaining *Miree*).

Moreover, in our system of federalism, "Federal and state law 'together form one system of jurisprudence.' " *Coeur d'Alene*, 521 U.S. at 276. Therefore, it is fundamental that "state courts share responsibility for the application and enforcement of federal law." *Howlett v. Rose*, 496 U.S. 356, 372-73 (1990). This Court consistently has expressed its "emphatic reaffirmation . . . of the constitutional obligation of the state courts to uphold federal law, and [its] expression of confidence in their ability to do so." *Coeur d'Alene*, 521 U.S. at 275, *quoting Allen v. McCurry*, 449 U.S. at 105. Accordingly, any "doctrine based on the inherent inadequacy of state forums would run counter to basic principles of federalism." *Id.*

Consistent with this fundamental constitutional scheme, it would be inappropriate to "imply" preemption based on the fact that a state tribunal may be called upon to interpret and apply a federal requirement in a suit seeking relief for conduct which violates that requirement. "When pre-emption of state law is at issue, we must respect the 'principles [that] are fundamental to a system of federalism in which the state courts share responsibility for the application and enforcement of federal law.' " *Johnson v. Fankell*, 520 U.S. at 922. Federalism and comity recoil at any notion that the states are divested of power to interpret federal law and to provide state remedies that are "consistent with pertinent federal laws." *DeCanas v. Bica*, 424 U.S. 351, 357 (1976).

And, the Court repeatedly has recognized that allowing a non-federal remedy for violation of a federal requirement can not, by definition, serve to impose the kind of conflicting substantive duties under state law, which have triggered implied preemption in cases such as *Geier*. Rather, the availability of a state damage remedy for conduct which violates federal requirements provides an additional incentive for compliance with the federal mandate and thus generally serves to advance rather than impair federal interests for purposes of implied preemption analysis. *E.g.*, *Medtronic*, 518 U.S. at 495-97; *CSX Transp.*, 507 U.S. at 668; *Shaw*, 463 U.S. at 101-02; *California v. Zook*, 336 U.S. 725, 736 (1949).

Given the above, it is singularly inappropriate to imply preemption of a private state-law remedy for conduct which violates a federal requirement on the ground that the state cause of action "impose[s] liability over and above that authorized by federal law." *English*, 496 U.S. at 89; *California v. ARC America Corp.*, 490 U.S. 93, 105 (1989); *Zook*, 336 U.S. at 736. Unless Congress expressly provides that federal law is to be the exclusive source of law with respect to private remedies in a particular area, either directly or through "field preemption,"[11] the states are free to apply their own law of remedies in private actions arising from conduct that violates federal law. *Id.*; *CSX Transp.*, 507 U.S. at 668; *Shaw*, 463 U.S. at 101-02.

2. In addition, this Court consistently has refused to accept the notion that allowing a state-law damage remedy for injuries caused by conduct in an area subject to federal regulation, would "conflict with" the federal regulatory scheme even where that scheme does not itself afford damage relief. Implied preemption is peculiarly inappropriate in such situations. The Court's opinion in *Silkwood* vividly illustrates this principle. In *Silkwood*, the issue presented to the Court was whether the plaintiff could recover punitive damages under state law on account of the escape of plutonium from a federally-licensed nuclear facility in violation of a federal regulation imposing a duty on the facility to "maintain the release of radiation 'as low as reasonably achievable.' " *Silkwood*, 464 U.S. at 241 & 245. This Court held that the claim survived implied preemption, notwithstanding the fact that the Court had previously ruled that "states are precluded from regulating the safety aspects of nuclear energy" and notwithstanding the fact that the Nuclear Regulatory Commission had determined that the defendant "complied with most federal regulations." *Id.* at 240-41 & 244. The Court emphasized that even though Congress intended to divest the states of authority to regulate the safety aspects of nuclear power plants, the legislative history of the federal nuclear

[11] *See, e.g., San Diego Building Trades Council v. Garmon*, 359 U.S. 236 (1959).

power legislation provided no indication that Congress even considered precluding the use of "state-law remedies" for individuals injured as a result of untoward conduct in the operation of nuclear power plants. *Id.* at 251. This, coupled with the fact that Congress provided no "federal remedy for persons injured by such conduct," made the Court loathe to imply that Congress had preempted such damage remedies, because it was "difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct." *Id.* at 251.

In reaching this conclusion, the Court rejected the position of the United States, as amicus curiae, that the award of punitive damages to plaintiff was implicitly preempted because it was at odds with the "federal remedial scheme" which allowed the Nuclear Regulatory Commission "to impose civil penalties . . . when federal standards have been violated." *Id.* at 257. Preemption, the Court ruled,

> should not be judged on the basis that the Federal Government has so completely occupied the field of safety that state remedies are foreclosed, but on whether there is an irreconcilable conflict between the federal and state standards or whether the imposition of a state standard in a damages action would frustrate the objectives of the federal law.

Id. at 239. The Court found "no such conflict or frustration in the circumstances of th[e] case." *Id.* at 256.

Although petitioner and the government would confine the operation of *Silkwood*'s "presumption" against implied preemption remedy to those instances in which preemption would leave an injured victim completely without compensation from any source,[12] the decision will not bear such a restrictive gloss. As the insolvency of AcroMed demonstrates here, the

[12] The government also argues that the presumption against preemption does not apply here because plaintiffs' claims "focus on an entity's obligations to truthfully disclose information to a federal regulatory agency," "an area of preeminent federal concern."

(Cont'd)

existence of a viable defendant outside the realm of a potential preemption defense in a given case is too ephemeral and unrelated to legislative intent to serve as a touchstone for implied preemption. Significantly, the opinion in *Silkwood* focused on the legislature's preemptive intent in terms of whether Congress considered the foreclosure of damage remedies in general and not in terms of the availability of damage relief to plaintiff from sources other than a given defendant. *Id.* at 250-51 & 256-58. Moreover, the issue in *Silkwood* was not whether the plaintiff could recover compensatory damages. *Id.* at 241, 245-46. All of the members of the Court appeared to accept that the plaintiff could recover such damages under state law consistent with implied preemption principles. *Id.* (majority); 464 U.S. at 276 n.3 (Powell, J. dissenting). Rather, the issue before the Court was whether the plaintiff could recover punitive damages which are, by definition, not intended to compensate but to perform the public policy functions of deterrence and punishment, functions arguably committed to the exclusive jurisdiction of the federal government. It is clear, then, that the Court's *Silkwood* holding creates a virtually irrefutable presumption against implied preemption of private damage remedies predicated on an alleged conflict with a federal remedial scheme.

(Cont'd)
See U.S. Br., at 9-10. However, the presumption against preemption is predicated on respect for the traditional role of the states in affording a damage remedy for invasion of the personal safety interests of its citizens. *See Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 518, 523 (1992). *Medtronic* makes it clear that the presumption is not displaced, simply because the injuries at issue result from a violation of the defendant's federal regulatory obligations, notwithstanding the government's obvious "concern" for compliance with federal regulations. *See Medtronic*, 518 U.S. at 44-45 & 495-97; *see also Hillsborough Cty., Fla. v. Automated Medical Labs.*, 471 U.S. 707, 719 (1985) (the fact that regulatory powers are entrusted to FDA pursuant to a complex regulatory scheme reflecting a matter of "national concern" does not justify departure from presumption against preemption). Since the plaintiffs' claims here focus on recovery of damages for the injuries sustained by them, and not on regulatory compliance as an end in itself, application of the presumption is appropriate.

B.

Application of these principles defeats any assertion that the FDCA impliedly preempts plaintiffs' right to recover damages under state law for the harms which they sustained as a result of Buckman's fraud.

Petitioner and the United States attempt to portray this claim as one which focuses on the relationship between the federal government and the entities it regulates and which presents a "novel" claim that has "no existence that is independent of the federal statutes . . . that require regulated entities to make certain disclosures to those federal agencies." *See* U.S. Br., 18. In this setting, they urge, allowing a private party to recover damages caused by fraud on the FDA "conflicts with" the supposedly unique federal interest in allowing the FDA to determine if it has been defrauded and its "exclusive" authority to resort to the remedies available to it under the FDCA. Pet'r. Br., 34-39; U.S. Br., 17-24.

When viewed through the lens of this Court's precedents, however, this portrait is inaccurate. This litigation involves a private dispute between Buckman and individuals who allege that they were physically harmed because Buckman's conduct was part of a scheme which led to the implantation of dangerous, untested devices within their spines.

Thus, unlike the case in a government enforcement action, the plaintiffs do not seek to establish fraud in order to redeem the public interest underlying truthful disclosure to federal regulators, but seek to vindicate their own individual interests in being free from bodily injury. Unlike the case in a government enforcement action, the plaintiffs' theory does not depend principally on the existence of a federal requirement, but relies on traditional theories of tort law which happen to be applicable because the defendant used the government, rather than another route, as the causal intermediary through which injury was produced. Unlike the case in a government enforcement action, plaintiffs do not seek any remedy committed to the prosecutorial discretion of the FDA. Instead, they seek a damage remedy — a remedy not provided by federal law, a remedy which has

traditionally been committed to the realm of state tort law and one which Congress never even "considered precluding" when it enacted the FDCA or the MDA. *See Medtronic*, 518 U.S. 490-92.

Because plaintiffs' claim is based on conduct that violates a federal requirement, there is no "irreconcilable conflict" between federal standards and the "state standards" which form the predicate for liability. Because the remedy requested is wholly private damage relief outside the ken of federal regulation, the claim does not conflict with any unique federal interest in enforcing an otherwise comprehensive regulatory scheme.

Indeed, if the claim for punitive damages survived implied preemption in *Silkwood*, despite the fact that the regulatory scheme there preempted all safety regulation by the states, despite the fact that the punitive damage remedy at issue was one which had penal ramifications beyond the private interests of the parties, and despite the fact that the federal regulators in that case actually determined that the defendant had complied with most of its obligations under federal law, then the damage claim here should certainly survive where this Court has held (in *Medtronic*) that there is no "field preemption," where compensatory damages are involved and where at least some federal regulators have determined that Buckman violated a federal law designed to protect persons in the position of plaintiffs from the kind of injury which they sustained. J.A. 124-26.

C.

The conclusion that plaintiffs' fraud claims are not impliedly preempted by federal medical device law ineluctably follows from the application of yet another principle of preemption jurisprudence. " 'The purpose of Congress is the ultimate touchstone' in every pre-emption case." *Medtronic*, 518 U.S. at 485, *quoting Retail Clerks Intern. Ass'n Local 1625, AFL-CIO v. Schermerhorn*, 375 U.S. 96, 103 (1963). Unless Congress intends preemption, there is none. Accordingly, where Congress has expressed itself on preemption in a statute, "Congress' intent

. . . is discerned from the language of the pre-emption statute and the 'statutory framework' surrounding it." *Medtronic*, 518 U.S. at 486, *quoting Gade v. Nat'l Solid Wastes Management Assn.*, 505 U.S. 88, 111 (1992) (Kennedy, J., concurring).

It follows from this that where a Congressional enactment includes an express, unambiguous provision regarding the preemption of specific areas of state law, a court should seldom imply a preemptive intent with respect to those areas, which is broader than that expressed by the legislature itself. *Cipollone*, 505 U.S. at 517; *Freightliner*, 514 U.S. at 288; *CSX Transp.*, 507 U.S. at 664. "Congress' enactment of a provision defining the pre-emptive reach of a statute implies that matters beyond that reach are not pre-empted." *Cipollone*, 505 U.S. at 517.

Section 360k of the MDA expresses Congress' preemptive intent with respect to medical devices. *Medtronic*, 518 U.S. at 484. Although ambiguous in some respects, the statute unambiguously provides that federal law does not preempt the states' ability to provide a remedy for conduct that violates the FDCA. *Id.* at 495-97 (plurality) & 513 (O'Connor, J.). The legislative intent in this regard is so lucid that this Court had little trouble reaching the unanimous conclusion that a state-law damage claim based on a "violation of federal regulations" is not preempted by section 360k, notwithstanding its explicit recognition of the FDA's exclusive prosecutorial discretion with respect to FDCA remedies and the absence of a federal damage remedy for conduct which violates FDCA requirements. *Id.* at 495 & 513. Therefore, in enacting the MDA, Congress necessarily determined that there was no implicit preempting "conflict" between allowing injured claimants to obtain a damage recovery under state law for MDA violations, and affording the FDA the right to employ the various public enforcement mechanisms given by the statute. To hold otherwise would result in a legal oxymoron — a ruling that the legislature clearly expressed an intent not to preempt state power to provide a damage remedy for violation of MDA requirements, but nonetheless "implicitly" intended to do so. Surely, that is not sensible.

In order to harmonize the obvious conflict between the "Identity of Requirements" holding in *Medtronic* and the position which it takes regarding implied preemption here, petitioner must postulate a distinction between claims arising from violations of FDCA requirements that involve disclosure to the FDA and claims arising from the remaining miscellany of regulatory directives. Under this preemptive calculus, the deceit claims would be impliedly preempted, while the other claims would survive preemption under *Medtronic*. Such a distinction is artificial.

To begin with, there is simply no difference between a state-law claim based on fraudulent disclosure to the FDA and a claim based on the violation of other types of FDCA requirements in terms of the regulatory "conflicts" which are claimed to require implied preemption. The regulatory enforcement responsibilities of the FDA and the remedies available to it are the same regardless of whether an FDCA violation occurs through deceit, culpable nondisclosure or through some other means. *See, e.g.*, 21 U.S.C. §§ 331-335c & 360(h). Accordingly, allowing a state-law damage claim for violation of federal disclosure requirements does not present any greater risk of "distorting the penalty scheme established by the FDCA," "interfering with the FDA's prosecutorial discretion," agency burden, or "conflicting adjudication," than allowing a damage claim for violation of other federal requirements such as unlawful promotion and mislabeling. Indeed, given the protective strictures which most jurisdictions attach to the litigation of fraud claims — the requirement that fraud be pleaded with particularity based on an adequate pre-complaint investigation and be proven by clear and convincing evidence[13] — these proffered "risks" are even more attenuated for deceit claims than for claims rooted in federal requirements not involving regulatory disclosures.

[13] *See, e.g.*, FED. R. CIV. P. 9(b); FED. R. CIV. P. 11; Pa. R. CIV. P. 1019(b); *Humana, Inc. v. Forsyth*, 525 U.S. 299, 301 (1999); *Trans Penn Wax Corp. v. McCandless*, 50 F.3d 217, 232 (3d Cir. 1995).

Second, insofar as Congress, in enacting section 360k, recognized the states' power to afford private remedies for violation of FDCA requirements in order to provide manufacturers with additional incentives to comply with their federal regulatory obligations, preemption of claims based on misrepresentations to the FDA is peculiarly inappropriate. *See Medtronic*, 518 U.S. at 495 ("The presence of a [state-law] damages remedy . . . provides another reason for manufacturers to comply with . . . 'requirements' under federal law") & 513 (O'Connor, J.) ("the threat of a [state-law] damages remedy will give manufacturers an additional cause to comply").

The FDA's determination of whether to approve the marketing of a drug, device or biologic is completely dependent on the information reported to it by the approval applicant. *See* Merrill, R.A., *Compensation for Prescription Drug Injuries*, 59 VA. L. REV. 1, 17 n.59 (1973). Therefore, the fulfillment of the agency's fundamental regulatory task depends entirely on full and truthful compliance with the FDA's disclosure requirements and "truthful responses to inquiries by the FDA." Green, M.D., *Statutory Compliance and Tort Liability: Examining the Strongest Case*, 30 U. MICH. J. LAW REFORM 461, 481 (1997); Garber, S., *Product Liability and the Economics of Pharmaceuticals and Medical Devices*, 127-28 (Rand 1993). Unfortunately, the history of the pharmaceutical-device industry is "littered with instances" of non-compliance in the form of intentional misrepresentations to the FDA or negligent failures to make required disclosures to the agency. Green, M.D., *Safety As An Element of Pharmaceutical Quality: The Respective Roles of Regulation and Tort Law*, 42 ST. LOUIS U.L.J. 163, 173 (1998). Indeed, in 1992, the Auditor General found so much fraud in the 510(k) process that the FDA amended its regulations to compel applicants to affirmatively state that their 510(k) notifications were truthful and not misleading. 57 Fed. Reg. 18062, 18064 (Apr. 28, 1992). And while the FDA has theoretical regulatory power to address such fraud, it is generally recognized that the agency does not have the resources to meet

this mandate in an effective way.[14] Accordingly, as one commentator put it, "[w]ithout regulatory resources to monitor and ensure universal compliance of this large, technologically complex, and informationally massive industry, we should expect that the tort system, rather than the FDA itself, will uncover instances of noncompliance with FDA [disclosure] standards." Green, 42 ST. LOUIS U.L.J. at 175.

If tort actions based on violations of FDCA requirements survive preemption under section 360k because of their perceived potential to secure compliance with such requirements, then deceit actions such as the present one should have a priority in avoiding the impediment of implied preemption.

D.

There is yet another reason why plaintiffs' fraud-on-the-FDA claims are not subject to implied preemption. In determining whether to imply preemption in a given instance, "the proper approach is to reconcile 'the operation of [the state and federal] schemes with one another. . . .' " *DeCanas*, 424 U.S. at 358. *See also CSX Transp.*, 507 U.S. at 668 (viewing state scheme as a "complement" to federal scheme); *Askew*, 411 U.S. at 332 (construction of federal statute as "one which allows . . . co-operation of the federal regime with a state regime"). Recognition of the states' power to make liability

[14] *See, e.g.*, Inspector General of the Department of Health and Human Services (HHS/IG), Report, *Investigative Devices: Four Case Studies*, OEI-05-94-00100 (Apr. 1995); General Accounting Office, *Medical Devices — FDA's 510(k) Operations Could be Improved*, GAO/PEMD-88-14 (Aug. 1988); HHS/IG, Report, *Internal Control Weaknesses in the Food and Drug Administration's Medical Device 510(k) Review Process*, A-15-89-00065 (Jul. 1990); H. R. Report by the Subcomm. on Oversight and Investigations of the Comm. on Energy and Commerce, *Less Than the Sum of its Parts — Reforms Needed in the Organization, Management and Resources of the Food and Drug Administration's Center for Devices and Radiological Health*, GPO PRINT No. 103-N (May 1993); *Fogal v. Steinfeld*, 620 N.Y.S.2d 875, 882-83, n.5 (N.Y. Sup. 1994) (citing and collecting articles and studies); Green, 30 U. MICH. J. LAW REFORM at 476-77.

determinations based on whether there has been fraud on the FDA is necessary to preserve an appropriate reconciliation between state tort law and federal regulatory law insofar as drugs and devices are concerned.

The tort law throughout the nation has not evolved without accommodating to the fact that there is a federal scheme which regulates the market entry of drugs and devices based on an informed risk-benefit analysis by the FDA. *E.g.*, RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6, cmt. b (1998). Given the thorough vetting of safety issues by the FDA, which takes place in connection with premarket approval of drugs and devices, emerging principles of state law would significantly constrict tort liability where the drug or device at issue has received premarket approval from the FDA. American Law Institute, *Enterprise Responsibility for Personal Injury*, Reporters' Study (Vol. II) at 95-101 (Weiler, ed. 1991); Green, M.D., *Statutory Compliance*, 30 U. MICH. J. LAW REFORM 461; RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 4 & cmt. e.

However, the law also recognizes that an FDA evaluation of safety is only as good as the information on which it is based and that it is the manufacturer, not the FDA, who supplies the information upon which the agency makes its approval determinations. *Id.* Accordingly, a manufacturer cannot avoid tort liability based on an FDA regulatory approval if the plaintiff demonstrates that the approval process "was tainted by the supplying of false information to, or the withholding of necessary and valid information from, the agency. . . ." RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 4, cmt. e.

The principal model of tort reform in the area of drug and device liability codifies the emerging common law approach. These statutes either foreclose tort liability altogether or preclude an award of punitive damages if the drug or device at issue received premarket approval from the FDA, except where the plaintiff shows that the defendant "knowingly withheld or misrepresented information required to be submitted to the FDA under its regulations." This model has been enacted as law in at

least six states[15] and proposed in the U.S. Congress (with the zealous support of the drug and device industry) during virtually every session from 1986 though the present.[16]

Permitting the award of damages based upon fraud on the FDA accommodates the primacy of federal regulation in protecting the public from unreasonably dangerous drugs and devices while assuring that individuals receive compensation when the proper operation of the federal regulatory system has been sabotaged by fraud as it was here. To hold that state courts lack the power to determine if the regulatory process was compromised by fraud because of "implied preemption" would undermine that accommodation. Ironically, it would also dismantle the principal tenet of tort reform espoused by the proponents of broad preemption in the field of drugs and devices.

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[15] *See* Mich. Comp. Laws Ann. § 600.2946(5); N.J. Stat. Ann. § 2A:58C-5; Ohio Rev. Code Ann. § 2307.80c; Or. Rev. Stat. § 30.927; Utah Code Ann. § 78-18-2; Arizona Rev. Stat. Ann. § 12-701.

[16] *See, e.g.*, S. 2760 (Product Liability Reform Act), 99th CONG., 2d SESS., § 303(c)(1)(B) (set forth in 132 CONG. REC. S12071-01) (Sept. 8, 1986) (amending original markup draft of S. 1999); S. 640 (Product Liability Fairness Act), 102d CONG., 2d SESS., § 303(c)(1)(B) (set forth in 138 CONG. REC. S13115-02 at S13117) (Sept. 9, 1992) (explained in S. REP. 102-215 (1991)); S. 687 (Product Liability Fairness Act), 103d CONG., 2d SESS., § 203(b)(2) (set forth in 139 CONG. REC. S4112-03 at S4149) (Mar. 31, 1993) (proposed amendments set forth in 140 CONG. REC. S7790-01 at S7754, S7793 & S7817) (Jun. 28, 1994); H.R. 956 (Common Sense Product Liability and Legal Reform Act of 1995), 104th CONG., 1st SESS., § 201(f) (reprinted and debated in 141 Cong. Rec. H2941-H2948) (Mar. 9, 1995) (passed, 141 CONG. REC. H3027 (Mar. 10, 1995)); H.R. 2425 (Medicare Preservation Act), 104th CONG., 1st SESS., § 15312 (set forth in 141 CONG. REC. H10147 at H10172) (Oct. 17, 1995); H.R. 2015 (Balanced Budget Act of 1997), 105th CONG., 1st SESS., § 4812(d)(B)(i) (set forth in 143 CONG. REG. H4416-01 at H4476) (Jun. 25, 1997); H.R. 2723 (BiPartisan Consensus Managed Care Improvement Act of 1999), 106th CONG., 1st SESS., § 412(b)(4) (set forth in 145 Cong. Rec. H9523-01 at H9554 (Oct. 7, 1999)).

E.

Petitioner and the government posit a rule of implied preemption akin to res judicata and collateral estoppel — that any determination necessary to sustain a cause of action cannot "conflict" with an express determination by a federal agency. *See* U.S. Br., 25-27; Pet'r. Br., 33-34. From this postulate, they argue that recognition of plaintiffs' fraud claim against Buckman is preempted because it would fail to effectuate the FDA's express determination to "grant[] market clearance for AcroMed's pedicle screws." *See* U.S. Br., 26-27.

There is substantial question as to whether the rule of preemption proffered by petitioner and the government applies where the allegedly preempting agency determination was based on fraud or other "affirmative misconduct." *See Arkansas La. Gas Co. v. Hall*, 453 U.S. 571, 583 (1981) (*Arkla*) (questioning the application of the "filed rate doctrine" where there is unadjudicated deceit).

There is also reason to question whether this rule could apply, consistent with the requirements of due process, to any agency determination that occurs outside of an APA rulemaking, adjudicative, or similar process. *See Davis v. Dep't of Labor and Industries of Wash.*, 317 U.S. 249, 256-57 (1942) (conditioning preclusive effect of agency determination on findings that result from adjudicatory process); *United States v. Utah Constr. and Mining Co.*, 384 U.S. 394, 421 (1966) (same).

Whatever the doctrinal limitations of this principle, one thing is clear. At a minimum, there must be a determination by a federal agency which is inconsistent with the plaintiffs' theory of liability. That minimum requirement is lacking in the present case.

Petitioner admits that in granting 510(k) clearance for AcroMed's plates and screws, the FDA made no determination with regard to the truthfulness of Buckman's representation that these components were intended for use in long bone fixation. *See* Pet'r. Br., 21. After the 510(k) clearance, representatives of the agency determined that they had been deceived concerning the intended use of the device components. J.A. 124. Accordingly, to the extent that plaintiffs assert that Buckman

defrauded the FDA, their claim does not conflict with any FDA determination.

Second, the relevant FDA determinations here are not at odds with the plaintiffs' cause of action. In seeking to establish a preempting conflict between the FDA's 510(k) determination and the plaintiffs' claims, the government twice says that "FDA granted market clearance for AcroMed's pedicle screws." *See* U.S. Br., 26. But these statements are wrong. The government's error in this regard actually demonstrates why the 510(k) determinations do not create a preempting conflict, even under the government's theory of implied preemption.

The fact is that the FDA specifically refused to grant 510(k) clearance "for AcroMed's pedicle screws." J.A. 101-06. In fact, the agency expressly told Buckman that AcroMed's pedicle screws could not be introduced into the market. *Id.*

Plaintiffs' claim is that Buckman subsequently deceived the FDA, and that as a result of this deception, devices intended for use in spine surgery — "pedicle screw fixation devices" — unlawfully entered the market where they were implanted in plaintiffs' spines causing serious injury. Nothing about that claim requires a finder of fact to determine that the FDA's determinations were "wrong" or otherwise "fails to give effect to" any FDA determination. In fact, recognition of the plaintiffs' claim actually serves to enforce the express determination made by the FDA that AcroMed's pedicle screw fixation devices should not be introduced into commerce because they posed serious risks that had not been adequately evaluated by accepted methods of science.

The principal cases cited by the government in support of implied preemption, *Arkla* and *Kalo Brick*, require that courts enforce pertinent agency determinations in private damage actions. *See Arkla*, 453 U.S. 571; *Chicago and N.W. Transp. Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311 (1981). In seeking to recover damages caused by a fraudulent scheme to market pedicle screw fixation devices in violation of an express government prohibition, that is exactly what the plaintiffs have asked the courts to do here.

F.

It has also been argued that plaintiffs' fraud claims are subject to implied preemption because permitting the litigation of those claims would pose an incidental burden on FDA resources. The adherents to this unique view of preemption describe two forms of agency burden which, in their view, justify depriving damage relief to persons injured by fraud. First, they claim that allowing litigation predicated upon the interactions between the FDA and those whom it regulates will inevitably result in discovery requests requiring the agency to produce thousands of documents and subject its employees to an obligation to provide testimony. Second, they hypothesize that recognition of a private civil damage claim based on false disclosures to the FDA will create an incentive to deluge the agency with unnecessary documents which will further contribute to the regulatory mire.

This theory of implied preemption is a unique one which is unsupported by a single authority. The reasons for this are obvious.

First, federal law reflects differential policies towards agency disclosure of information. Importantly, there is a strong federal policy supporting full public disclosure of documents used, created and relied upon in the FDA regulatory process. This is reflected in the Freedom of Information Act and in the regulations promulgated by the FDA. *See, e.g.*, 5 U.S.C. § 552; 21 C.F.R. § 20.1, *et seq.* Therefore, preemption of a state cause of action based on the document production burden imposed on the government would actually be contrary to Congressional intent. It is, therefore, inconsistent with the requirement that implied preemption be employed only where state law presents an obstacle to accomplishing the objectives of Congress.

Of course, there are principles of federal law such as the "deliberative process privilege" and the "*Touhy*" doctrine, which are based on defined federal interests in limiting the availability of testimony or document disclosure by agency officials under certain discreet circumstances. *See United States ex rel. Touhy v. Ragen*, 340 U.S. 462 (1951) (agency's power to promulgate

"housekeeping" regulations restricting employees from testifying in order to conserve agency resources); 21 C.F.R. § 20.1 (FDA's "*Touhy*" regulation); *Redland Soccer Club, Inc. v. Dep't of Army of U.S.*, 55 F.3d 827, 853 (3d Cir. 1995), *cert. denied*, 516 U.S. 1071 (1996) (deliberative process privilege). However, it is certainly more sensible to protect these limited governmental interests through a direct, and appropriately targeted application of these well-developed principles of federal law than through a broad preemption blunderbuss.

Second, the "discovery burden" theory of implied preemption which is espoused by our opponents is impossible to cabin. Irrespective of fraud claims, the typical pharmaceutical-device products liability litigation inevitably generates requests for the FDA to produce an enormous volume of documents and testimony concerning the interactions between the defendant and the agency.[17] This is not because plaintiffs usually claim that the agency was defrauded, but because the regulatory background is always a central factor underlying both the prosecution and defense of litigation of this sort. If the "burden" on the government created by such discovery requests was preemptive of the underlying liability claims, then all pharmaceutical-device claims would be preempted. Indeed, given the important role of federal regulation in everything from automotive safety to zoology, the potential production burden on the government could preempt nearly all civil litigation. The absurdity of this potential result counsels rejection of this type of "burden" as a basis for implied preemption. *E.g.*, *Ingalls Shipbuilding, Inc. v. Director, Office of Workers' Compensation*

[17] Thus, for example, in the recent "FenPhen" Diet Drug Litigation, the plaintiffs did not make any substantive claim of fraud on the FDA. Nevertheless, in that litigation, the FDA produced 35,000 pages of agency records in response to a federal court subpoena and offered to make several of its employees available for testimony. *See* U.S. Mem. of Law in Opp. to PMC's Motion to Compel, Dkt. No. 201402, MDL 1203 (E.D. Pa.); *see also In Re: Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prod. Liab. Litig.*, MDL 1203, PTO 1461 (Oct. 12, 2000).

Programs, U.S. Dept. of Labor, 519 U.S. 248, 261 (1997) (presumption that legislature does not intend an absurd result); *United States v. Rodgers*, 466 U.S. 475, 484 (1984) (same).

Finally, the argument that allowing damage liability for violation of FDA disclosure requirements will cause manufacturers to deluge the agency with irrelevant information which they otherwise would have withheld is based on complete speculation. What evidence is there to suggest that the possibility of paying damages to plaintiffs in an individual case will create a materially higher incentive to irrelevant disclosure than the possibility of criminal sanctions, fines, penalties, and product recalls which the FDA has the power to mete out? There is none. There is no legal principle which would allow a reed of speculation so slender to usurp the states' ability to afford damage relief.

G.

There remain three miscellaneous arguments which have been advanced in support of implied preemption. However, they do not merit extensive treatment.

1. First, it is claimed that the promulgation of the FDA's 1998 regulation reclassifying pedicle screws conflicts with plaintiffs' fraud claims. It is hard to see how. The government itself concedes that in promulgating that regulation, the FDA did not make any adjudication concerning the lawfulness of past conduct. U.S. Br., Pet. Stage, 14. The government concedes that the promulgation of that regulation in 1998 was prospective and could not validate unlawful behavior which preceded the regulation. *Id.* Finally, the regulation does not support a claim that Buckman's fraud was inconsequential on the grounds that it represents a regulatory determination that pedicle screw devices are properly subject to less regulation than that afforded to them at the time of Buckman's fraud in the mid-1980s. *See* Pet'r. Br., 39-40. The 1998 reclassification regulation allows Class II treatment of pedicle screw devices for a narrow range of indications subject to numerous special controls as to design, testing, material composition, biocompatability and labeling, which provide protections that the plaintiffs never received.

21 C.F.R. § 888.3070. If anything, the regulation demonstrates the risks that plaintiffs were exposed to because of Buckman's fraudulent evasion of the FDA's determination that pedicle screws should not reach the market without additional testing and controls. Consequently, as the government itself concedes, the reclassification regulation creates no preempting conflict with plaintiffs' claims. *See* U.S. Br., Pet. Stage, 14.

2. It is also claimed that permitting the assertion of plaintiffs' fraud claims will undercut a supposed federal policy to promote the development of "off-label" uses — those uses that have not been subject to FDA approval or clearance. However, the policy reflected in the FDCA is that such untested uses are "treacherous."[18] Thus, while recent amendments to the FDCA permit manufacturers to provide limited "educational materials" regarding "off-label use" under very narrow circumstances, the promotion and clinical development[19] of "off-label uses" without FDA approval or clearance is generally illegal. *See* pp. 1-2 & 6, *supra*; *see generally*, Weeks, E., *Is It Worth the Trouble? The New Policy On Dissemination of Information on Off-Label Drug Use Under the Food and Drug Administration Modernization Act of 1997*, 54 FOOD & DRUG L.J. 645 (1999). Accordingly, to the extent that recognition of plaintiffs' cause of action creates incentives to comply with federal law concerning the unlawful development, testing, marketing and promotion of unapproved uses, it is in harmony — not conflict — with the relevant objectives of federal law. Indeed, this is a reason not to imply preemption.

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[18] *See* pp. 1-2, *supra*. To the extent that the law allows physicians to use drugs or devices "off label," it does so as a consequence of the fact that the FDCA is limited to regulation of the distribution of drugs, devices and biologics and does not reach the "practice of medicine" by physicians. Nightingale, S.L. *Unlabeled Use of Approved Drugs*, DRUG INFORMATION JOURNAL, 26:141-47 (1992).

[19] If a manufacturer wishes to develop clinical evidence to support approval or clearance of an "off-label" use, it may only do so pursuant to an investigational device exemption from the FDA. *See* 21 U.S.C. § 360j(g); 21 C.F.R. § 812, *et seq.*

3. Finally, petitioner and its industry supporters invoke preemption as a specie of tort reform, urging that if the present fraud claims are not preempted, plaintiffs will routinely seek to avoid the effect of an FDA approval or clearance by making specious claims of fraud. This argument is a political one not properly conjured in aid of a judicial finding of implied preemption. *Geier*, 120 S. Ct. at 1932 (Stevens, J., dissenting). Even as a political argument it fails. The argument assumes that because an individual is a plaintiff, he or she will automatically file a baseless claim. Certainly, there is no evidence for this. The states of Michigan, Ohio, New Jersey, Oregon, Utah and Arizona have, for some period of time, had a scheme that allows plaintiffs to recover punitive damages in pharmaceutical-device cases only where they prove fraud on the FDA. *See* fn. 15, *supra*. Is there any evidence that plaintiffs have abused this scheme? It appears that there is not, particularly given that these statutes are touted as a model of tort reform.

Also, claims of fraud are attended by procedural safeguards, not attached to other causes of action, which provide substantial protection against specious assertions. These include the requirement that fraud be pleaded with particularity based on an adequate pre-complaint investigation and that fraud be demonstrated by clear and convincing evidence. *See* fn. 13, and accompanying text, *supra*.

In those rare occasions where there is abuse, sanctions or damage liability are available and afford appropriate remedies. *See, e.g.*, FED. R. CIV. P. 11; 28 U.S.C. § 1927; *Alyeska Pipeline Service Co. v. Wilderness Society*, 421 U.S. 240, 248-59 (1975); RESTATEMENT (SECOND) OF TORTS § 674. However, it would be ironic, indeed, if the courts retained the power to award damages for the injuries caused by fraudulent litigation, but were ousted of that power where the injuries at issue were caused by fraudulent regulatory submissions.

CONCLUSION

For the foregoing reasons, the decision of the United States Court of Appeals for the Third Circuit should be affirmed.

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In the Supreme Court of the United States

THE BUCKMAN COMPANY,

Petitioner,

v.

PLAINTIFFS' LEGAL COMMITTEE,

Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Third Circuit

REPLY BRIEF FOR PETITIONER

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REPLY BRIEF FOR PETITIONER

Plaintiffs represent that they "seek damages under conventional concepts of state tort law" (Pl. Br. 15). But there is nothing "conventional" about plaintiffs' claim. A judge or jury, applying *state* law, would have to decide what the FDA actually knew about the medical devices at issue, whether the FDA believed that the information allegedly withheld was material, and what regulatory actions the FDA would have taken if certain disclosures had been made. And in order for plaintiffs to prevail, a judge or jury, applying *state* law, would have to find that the medical devices at issue should not have been on the market, even though the FDA has conclusively determined, as a matter of *federal* law, that the devices were at all times properly on the market.

It is difficult to imagine a state tort claim that has a greater potential to conflict with federal law. For this reason, the Solicitor General, as well as every federal court of appeals to consider the question (except for the court below), have concluded that "fraud on the agency" claims are preempted by federal law. Indeed, just three weeks ago the Sixth Circuit held that such claims are preempted because "actions for fraud on the FDA would allow individual juries to undertake a counterfactual FDA review, and conclude that the FDA would not have approved the device," and because "a fraud claim premised on false representations to the FDA * * * would conflict with well-established precedent that no implied private action exists under the FDCA." *Kemp* v. *Medtronic, Inc.*, No. 99-3720, slip op. 35-36 (Nov. 1, 2000).

In our opening brief, we explained why plaintiffs' "fraud on the FDA" claim is both expressly and impliedly preempted by federal law. In response, plaintiffs do not dispute that their fraud claim imposes *state* requirements that are subject to express preemption under 21 U.S.C. § 360k(a). They contend, however, that the *federal* disclosure requirements applicable to the devices were not "specific" or "different" enough from the state requirements to qualify for express preemption. As for implied preemption, plaintiffs make no effort to address the many ways in

which their fraud claim would conflict with and frustrate federal law. Instead, they rely almost entirely on catchwords such as the "presumption against preemption," "basic notions of federalism," and "incentives for compliance with federal mandates." Pl. Br. 15-16, 33. In the end, much of plaintiffs' brief is devoted to addressing arguments that were never made and to describing facts that are largely irrelevant to the issues presented in this case.[1]

I. PLAINTIFFS' "FRAUD ON THE FDA" CLAIM IS EXPRESSLY PREEMPTED

We explained in our opening brief (at 17-24) that plaintiffs' claim is expressly preempted under the plain language of 21 U.S.C. § 360k(a) because, if allowed to proceed, it would impose *state* disclosure "requirements" relating to the "intended use" of the AcroMed medical devices that are "different from, or in addition to" the *federal* disclosure requirements relating to intended use that apply to the very same devices. We further demonstrated (at 25-30) that the state and federal disclosure requirements at issue in this case are "specific" in every relevant sense: they arise from the particularized application of state and federal laws to individual devices (and no others); they impose

[1] Plaintiffs' brief is replete with factual assertions that are incorrect, drawn from portions of plaintiffs' affidavits that were controverted by other evidence, or dependent exclusively upon extrarecord materials. For example, plaintiffs incorrectly state that the FDA concluded that it had been defrauded by Buckman. See Pl. Br. 10 (citing J.A. 124, an FDA letter to *AcroMed* that does not mention Buckman or say that the agency was defrauded). Plaintiffs also assert (Pl. Br. 9) that it was "physically impossible" to use the AcroMed "plates and screws in long bone repair," but their only support for that "fact" is an affidavit that was attached to plaintiffs' own comments in an FDA proceeding (which are not part of the record of this case). Moreover, plaintiffs' lengthy description of Buckman's supposed "fraud" (Pl. Br. 9-12) focuses largely if not entirely on (a) post-clearance conduct (b) by AcroMed (c) that had nothing to do with Buckman and is properly addressed through enforcement of the FDA's rules against unlawful marketing practices.

obligations to make specific disclosures that concern each device's "intended use"; and they are the product, on the federal side, of active and particularized review and consideration by the FDA.

Plaintiffs respond that there is no express preemption because the pertinent federal disclosure requirements are (1) identical to the disclosure requirements imposed under plaintiffs' "fraud on the agency" claim and (2) not sufficiently "specific" to come within Section 360k(a). Neither argument is correct.

A. The State And Federal Requirements Are Different

In our opening brief (at 19-24), we showed that plaintiffs' "fraud on the agency" claim is predicated on Buckman's purported obligation, under state law, to disclose to the FDA that AcroMed subjectively desired, hoped, or expected that the bone screws, plates, rods, and hooks of the VSP and ISOLA Systems — although labeled for use only in bones other than the spine — would be used by physicians for spinal fixation. We further demonstrated that federal law, in contrast, does *not* impose any requirement that a 510(k) submission disclose how a manufacturer subjectively intends that a device will be used, because subjective intent is irrelevant under the MDA. The "intended use" that must be disclosed in a 510(k) submission is the use (as listed in the labeling) for which FDA marketing clearance is sought. See also PhRMA Br. 16-20; MDMA Br. 5-13.

Both plaintiffs and the government concede that under federal law "a manufacturer is *not* required to disclose *every* foreseeable use of a device that it secretly desires." U.S. Br. 15 (emphasis added); see also Pl. Br. 28 (acknowledging that 510(k) submission need not "list every potential use of a device"). They also concede that the concept of "intended use" under federal law is "objective" rather than "subjective." See U.S. Br. 14-15; Pl. Br. 27. Yet the government contends (as do plaintiffs) that Buckman was required to disclose the foreseeable and subjectively intended use of spinal fixation because, according to the allegations in plaintiffs' complaint, "at the time of the [510(k)] application, [the] manufacturer plan[ned] to promote and distribute [the] device

exclusively for [that] use." U.S. Br. 15 (emphasis added); see also Pl. Br. 28.

The argument that the "intended use" that must be disclosed in a 510(k) application extends beyond labeling claims cannot be reconciled with the plain language of the MDA, which defines "substantial equivalence" as consisting of situations where the proposed device "has the same intended use as the predicate device" (21 U.S.C. § 360c(i)(1)(A)) and which unequivocally provides:

> *Any* determination by the [FDA] of the *intended use* of a device *shall be based upon the proposed labeling* submitted in a report for the device under [Section 510(k)].

Id. § 360c(i)(1)(E)(i) (emphasis added) (see App., *infra*, 2a).[2] As the accompanying Senate Report explained, this provision was added to make explicit Congress's intent in passing the MDA "that device * * * approval decisions be made based on the *intended use of devices as described in the labeling*. * * * No considerations outside of the proposed labeling for the § 510(k) device should bear on the question of whether or not the proposed labeling of the newer device is compatible with the labeling of the predicate device." S. REP. NO. 105-43, at 27 (1997) (emphasis added). Accord H.R. REP. NO. 105-307, at 25 (1997). The statutory text and legislative history thus firmly establish that "intended use" means the use *identified in the device's labeling*. See also PhRMA Br. 17-20; MDMA Br. 7-12.

In light of this statutory language, the government is forced to concede that, under Section 360c(i)(1)(E)(i), the "FDA is required to confine its inquiry to the intended use identified in the proposed labeling * * * when it makes a substantial equivalence determination." U.S. Br. 16 n.2. Since Buckman's "intended use"

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[2] Although this statutory language was added after the 510(k) submissions at issue here were made, the amendment corresponds to Congress's original intent and thus "do[es] not alter the analysis" (U.S. Br. 15 n.2).

representations were made in the context of just such a "substantial equivalence determination," the government's concession should end the debate on this point. The government maintains, however, that Section 360c(i)(1)(E)(i) "does not relieve manufacturers of their obligation * * * to truthfully inform FDA of a device's 'intended use' as that term is defined in FDA's 'intended use' regulation, 21 C.F.R. 801.4." U.S. Br. 15 n.2; see also Pl. Br. 26-29 (arguing that Section 801.4's definition of "intended use" applies to 510(k) submission). Under Section 801.4, "intended use" means the use that "will be revealed by all the manufacturer's 'expressions' and 'the circumstances surrounding' the device's 'distribution.'" U.S. Br. 15.

This argument is wrong. To begin with, it is refuted by the plain language of 21 U.S.C. § 360c(i)(1)(E)(i), which specifically provides that, for purposes of 510(k) submissions and substantial equivalence determinations, "*[a]ny* determination by the [FDA] of the intended use of a device *shall be based* upon the proposed labeling submitted" (emphasis added). It also is refuted by the FDA regulation that applies specifically to "intended use" representations *in the context of 510(k) applications*. That regulation — 21 C.F.R. § 807.87(e) — requires applicants to submit "[p]roposed labels, labeling, and advertisements sufficient to describe the device, *its intended use*, and the directions for its use" (emphasis added) (see App., *infra*, 5a). This wording confirms that "intended use" is not a statement of the applicant's subjective intent or expectation but rather a representation in the *labeling* that serves to define the scope of marketing approval that is being requested. The "intended use" that must be identified under 21 C.F.R. § 807.87 is the "intended use" that must be the exclusive basis for the FDA's substantial equivalence determination under the statute.

It is telling that, rather than focus on the statutory or regulatory provisions that expressly govern "intended use" representations in the 510(k) context, plaintiffs and the government rely on a different "intended use" regulation, 21 C.F.R. § 801.4 (see App., *infra*, 4a). As explained in our opening brief (at 23 n.3), however,

Section 801.4 does not apply to 510(k) applications. It is part of the *general labeling* provisions (Title 21, Chapter 1, Subchapter A, Part 801), *not* the provisions governing *premarket notifications* (Title 21, Chapter 1, Subchapter H, Part 807, Subpart E). By its plain terms, Section 801.4 applies *only* to three regulations, none of which is at issue here: 21 C.F.R. § 801.5, which governs "adequate directions for use"; 21 C.F.R. § 801.119, which governs "in vitro diagnostic products"; and 21 C.F.R. § 801.122, which governs medical devices "intended for processing, repacking, or use in the manufacture of another drug or device." Moreover, while Section 801.4 requires warnings in certain circumstances, it does *not* provide that a foreseeable off-label use creates a new "intended use."

It is entirely sensible to require a device manufacturer to include warnings about foreseeable, but unapproved, uses in the labeling for a device following clearance of the device for marketing. As Section 801.4 itself acknowledges, a device's use "may change after it has been introduced into interstate commerce by its manufacturer." In the context of a 510(k) submission, however, equating "intended use" with "foreseeable use," "subjectively intended use," or even use that an applicant expects will be a part of "the manner in which * * * the device will be characterized by its sellers and distributors" (Pl. Br. 28) would be wholly unworkable, as we showed in our opening brief (at 24) and as plaintiffs and the government do not dispute.[3]

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[3] As the government points out (Br. 15-16 n.2), FDA has the authority under 21 U.S.C. § 360c(i)(1)(E)(i) to require a warning with respect to a "use of a device not identified in the proposed labeling" if the agency determines that such off-label use "could cause harm." Like Section 801.4, this section merely authorizes the FDA to require a warning as part of the 510(k) clearance process if it has information regarding a potentially harmful off-label use. But an unclaimed use for which the agency may require a warning is still not an "intended use" for purposes of the substantially equivalence determination, and thus a manufacturer does not commit fraud by failing to mention it as

(continued...)

Finally, it is worth emphasizing that the FDA found that the screws, plates, rods and hooks involved in this case were in fact similar, in their physical characteristics, to devices that were commercially available prior to 1976. The FDA also determined that, when evaluated in light of the "intended use" identified in the pertinent 510(k) submissions, the devices qualified as "substantially equivalent" to pre-1976 devices for long bone use. That means that screws and plates just like AcroMed's, presumably marketed for long bone use, were already on the market in 1985. And, of course, there was no reason why those plates and screws could not lawfully have been used by surgeons for spinal applications. In light of these facts, and the basic purpose of Section 510(k) to allow competition with grandfathered devices, it was perfectly consistent with the statutory scheme for AcroMed to seek market clearance for its devices, labeled for long bones, in the hope that surgeons would similarly use their products for spinal surgery. Of course, AcroMed could not *market* the devices for that use; but that is a matter addressed through the FDA's *marketing* regulations, not its regulations governing disclosures of intended use *prior to marketing*.[4]

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[3] (...continued)
part of its 510(k) submission. See PhRMA Br. 18-19 & n.10.

[4] Plaintiffs assert that, if the "intended use" determination for purposes of 510(k) were limited to the labeled use, the MDA "would have virtually no effect" because a manufacturer could "reach the market without regulatory constraint" through "the simple expedient of submitting a proposed label reflecting a pretextual use which matched a pre-enactment use." Pl. Br. 28. But Congress itself has mandated this definition of "intended use." In any event, plaintiffs' argument ignores both the applicant's duty to show that the proposed device has the same technological characteristics as the predicate device (see 21 U.S.C. § 360c(i)(1)(A); 21 C.F.R. § 807.87(f)) and the independent restrictions imposed by the FDA's "regulations prohibiting marketing for off-label uses." Pet. App. 28 (Cowen, J., dissenting).

B. The Federal Disclosure Requirements Are Specific

As noted in our opening brief (at 28-29, 46-47, 49), the "specificity" concept has at least two possible meanings. A requirement can be "specific" in its *content* (like Justice Breyer's 2-inch wire requirement, which is specific when compared to a more generalized duty to use reasonable care in the design of a product). Alternatively, a requirement can be "specific" in its *applicability* (as where it applies to a single device or a single class of devices). The federal disclosure requirements at issue in this case are "specific" in both content and applicability.

In arguing otherwise, plaintiffs pointedly avoid explaining which of the various meanings of "specificity" they endorse or why. See Pl. Br. 20-21. The government, in contrast, acknowledges the fundamental ambiguity but explains that under the FDA's exemption regulation, a federal requirement that is specific *either in content or in applicability* will trigger preemption under Section 360k(a). See U.S. Br. 12. On the issue of what is meant by "specificity" in a requirement's "applicability," the government suggests that federal requirements qualify if they apply "to a specific device *or set of devices*." *Ibid.* (emphasis added). Thus, the government concedes that a federal requirement may satisfy the "specificity" test even if it applies to more than a single medical device. At the same time, however, the government takes the position that the disclosure requirements involved here are not "specific" enough because they "appl[y] to all devices that must undergo the Section 510k clearance process, *not just pedicle screw devices*." *Ibid.* (emphasis added).

1. The government's position is impossible to square with common sense or any rational congressional purpose underlying the MDA's express preemption clause. Under the government's view, if the disclosure requirements imposed by 21 C.F.R. § 807.87 applied *only* to "pedicle screw devices," then the requirements *would* trigger preemption under 21 U.S.C. § 360k(a). In other words, if the FDA took the *identical* disclosure requirements now covered by Section 807.87 and promulgated

thousands of identical versions of that regulation, each applicable to one type of device, then each of the regulations would trigger express preemption. But because the agency has chosen to issue a single regulation applicable to all 510(k) applications, state law may impose different or additional disclosure requirements on device manufacturers without running afoul of Section 360k(a). Why would Congress have intended such an bizarre result?[5]

The government also offers no plausible reason why a federal requirement's applicability to a "set of devices" that consists of a single *regulatory* class is not enough to bring the requirement within Section 360k(a).[6] That position is inconsistent with the FDA's past regulatory interpretation and practice as well as with congressional intent. As noted in our opening brief (at 30 n.6), the FDA has acknowledged that federal requirements that apply to the regulatory class of PMA devices trigger express preemption. See 43 Fed. Reg. 18661, 18664 (1978). In addition, the House Report accompanying the MDA gave as an example of state laws that should be granted an exemption from preemption under 21 U.S.C. § 360k(b) a California law that required "premarket approval of all medical devices." H.R. REP. NO. 94-853, at 45-46 (1976). There

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[5] The statutory requirement of "substantial equivalence" applies to *all* devices that undergo the 510(k) clearance process, not just pedicle screw devices. 21 U.S.C. § 360(k). Therefore, under the plaintiffs' and the government's "specificity" rationale, a state law requiring that new pedicle screw devices be "identical," rather than "substantially equivalent," to pre-1976 devices would not be preempted by Section 360k(a).

[6] As explained in our opening brief (at 30 n.6), the federal disclosure requirements at issue in this case apply only to a single regulatory class of medical devices: those for which 510(k) clearance is sought. Accord U.S. Br. 12. The disclosure requirements do not apply to investigational devices or devices seeking premarket approval under Section 360e. For that reason, plaintiffs are wrong when they say (Pl. Br. 20) that the federal requirements at issue in this case "are no more specific than the Good Manufacturing Practices and labeling regulations" at issue in *Medtronic*.

would have been no need for an exemption if federal PMA requirements did not trigger express preemption in the first place. If federal requirements that target the regulatory class of PMA devices are "specific" enough to trigger preemption, so too must be requirements targeting 510(k) devices.

Moreover, there is no plausible distinction between the federal disclosure requirements at issue in this case and the examples given by the government of federal requirements that concededly "appl[y] to a specific device or set of devices" (U.S. Br. 12) and thus trigger express preemption. Those examples include, for example, federal requirements that apply to (1) all medical devices that contain natural rubber (21 C.F.R. § 801.437) and (2) all medical devices containing any patient cable or electrode lead wire (21 C.F.R. § 898). But according to the FDA itself, the "natural rubber" regulation applies to *43 different categories* of medical devices, including catheters, latex gloves, tracheal tubes, balloons, orthodontic headgear and bands, condoms, enema kits, elastic bandages, ophthalmic eyeshields, irrigating syringes, surgical masks, tourniquets, water bottles, elastic binders, crutch pads and tips, intestinal splinting tubes, and in vitro diagnostic devices. 63 Fed. Reg. 50660, 50673-50676 (1998). Moreover, FDA has estimated that these 43 categories comprise "approximately 17,600" different models of medical devices. *Id.* at 50676. The government offers no explanation why such broadly applicable requirements trigger express preemption but the disclosure requirements at issue in this case do not.

2. There is a second, independent reason why the federal disclosure requirements are sufficiently specific *in applicability* to trigger preemption under 21 C.F.R. § 808.1(d): they have been *specifically applied* to the *particular* medical devices at issue in this case. Contrary to the government's suggestion, there is no analytical difference between (1) the process by which a generally applicable state tort law "duty of care * * * is made applicable to a device through application in litigation," which the government admits can lead to "specific" requirements (U.S. Br. 12-13 n.1), and (2) the process of specific application of federal requirements

to individual devices that occurred in this case.[7]

Plaintiffs and the government argue that this comparison is invalid because the FDA is not required "to evaluate the truthfulness of a 510(k) submission with respect to intended use" (Pl. Br. 20) and "there is no indication in this case that FDA determined when it cleared the device under Section 510(k) that petitioner and AcroMed had satisfied all applicable duties of disclosure" (U.S. Br. 13 n.1). But the existence or effect of the disclosure requirements imposed on Buckman is in no way dependent upon what the FDA did with the information after Buckman complied. Regardless of what the agency did, or what it was required to do, with the information, or whether it made an assessment of Buckman's compliance, the fact remains that Buckman was *required to make specific disclosures in the 510(k) submission for specific devices*. There is no difference between that process and what occurs when a common law claim "is made applicable to a device through application in" litigation. U.S. Br. 12-13 n.1. In any event, the fact that the FDA granted the 510(k) applications after prolonged scrutiny shows conclusively that the agency determined that the requirements had been met.

3. The federal disclosure requirements are also "specific" in their *content* and, according to the government's position, thus trigger preemption on this alternative basis under 21 C.F.R. § 808.1(d)(1). The federal disclosure requirements narrowly and specifically focused upon "intended use" disclosures concerning *these particular devices*. And, in response to these federal requirements, Buckman and AcroMed made detailed and particularized statements about the intended use of the individual devices — again, disclosures *required* by federal law. The

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[7] The fraud duty underlying plaintiffs' claim applies, potentially, to products other than medical devices. Yet as demonstrated in our opening brief (at 26-27), that state-law duty has been applied with great specificity in this litigation, as set forth in the detailed allegations of plaintiffs' complaint. Neither plaintiffs nor the government dispute this.

disclosure requirements here are at least as specific *in content* as other requirements that the government concedes would trigger express preemption because they are "stated with specificity." U.S. Br. 12. See, *e.g.*, 21 C.F.R. § 801.420(c)(6)(i) (requiring statements in user instruction brochures for hearing aid devices not to be "false and misleading"); *id.* § 801.437(c) (requiring certain statements in the labeling of devices containing natural rubber to be "prominently and legibly displayed").

Indeed, one of the regulations identified by the government (U.S. Br. 12) as being "stated with specificity," 21 C.F.R. § 898, contains a disclosure requirement concerning "intended uses" that is indistinguishable in content from that involved in this case. Under 21 C.F.R. § 898.14(a), a manufacturer may seek an exemption or variance from certain performance standards applicable to devices containing electrode lead wires or patient cables, but must first disclose the device's "intended use(s)" by submitting "representative labeling." If the representations required of Buckman in the 510(k) process had been made in an application for an exemption under Section 898.14(a), there would be no question, under the government's own admission, that the federal disclosure requirement would trigger preemption under Section 360k(a). There is no rational basis for a different conclusion here.

II. PLAINTIFFS' CLAIM IS IMPLIEDLY PREEMPTED

Even if plaintiffs' "fraud on the agency" claim is not expressly preempted by the MDA, it is impliedly preempted. As explained in our opening brief (at 31-45), plaintiffs' claim, if permitted to proceed, would frustrate the FDA's interest in valid, final, and correct decisionmaking; conflict with the MDA statutory scheme; and interfere substantially with the operations of the federal agency. The Solicitor General agrees that plaintiffs' claim is impliedly preempted, explaining that if allowed to go forward, it would intrude upon an area of preeminent federal concern, conflict with important federal interests in permitting the FDA to decide for itself whether it was defrauded (and, if so, what remedy to

seek), and nullify the FDA's decision to clear the relevant devices for marketing. U.S. Br. 16-30.

Plaintiffs have now abandoned the argument, which they pressed below and which was the basis for the Third Circuit's decision, that this Court's decision in *Medtronic* resolved the implied preemption issue in their favor. As the Sixth Circuit recently explained, in disagreeing with the decision below, "nothing in [*Medtronic*]" undercuts a finding of implied preemption because the plaintiffs in that case "did not present a 'fraud on the FDA' claim" and because such claims simply cannot be equated with "'parallel' state law requirements as contemplated by" *Medtronic*. *Kemp*, slip op. 33-34.

Although plaintiffs decline to defend the basis for the lower court's ruling, they do advance a variety of arguments aimed at incorporating the MDA-specific limits on express preemption recognized in *Medtronic* into the law of implied preemption. Those efforts, and plaintiffs' other responses to our implied preemption arguments, are wholly unpersuasive.

1. Plaintiffs first assert that where Congress has enacted an express preemption provision, "a court should seldom imply a preemptive intent * * * which is broader than that expressed by the legislature itself." Pl. Br. 37. In making this argument, plaintiffs rely on a serious misreading of *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504, 517 (1992), without acknowledging that their contention has been repudiated by subsequent decisions of this Court. See *Geier* v. *American Honda Motor Co.*, 120 S. Ct. 1913, 1919-1920 (2000); *Freightliner Corp.* v. *Myrick*, 514 U.S. 280, 287-289 (1995). Just last Term in *Geier*, the Court held that an express preemption clause "does *not* bar the ordinary working of conflict pre-emption principles." 120 S. Ct. at 1919.

Equally incorrect is plaintiffs' suggestion that *Medtronic*'s framework for analyzing express preemption under the MDA — and in particular the distinction between "requirements" and "remedies" (Pl. Br. 29-30) — should be superimposed on the implied preemption analysis in this case. No issue of implied

preemption was raised or resolved in *Medtronic*, and in fact the Court emphasized that common law claims that are not subject to express preemption can still be "preempted under conflict preemption analysis." 518 U.S. at 503; see also *id.* at 507-08 (Breyer, J.). Congress presumably takes the trouble to enact an express preemption clause only where it wishes to *supplement* the displacement of state law that occurs by virtue of the Supremacy Clause and through the ordinary workings of implied preemption principles. See *Crosby* v. *National Foreign Trade Council*, 120 S. Ct. 2288, 2302 (2000). And plaintiffs are simply wrong to suggest that state remedies are incapable of conflicting with federal remedies as long as they purport to enforce the same "requirement." If, for example, the FDA were to find that an applicant made misrepresentations in a 510(k) request but that, for public health reasons, the medical device should remain on the market, it surely would conflict with federal policies for state law to penalize the manufacturer for not removing the device from the market.[8]

2. Plaintiffs next argue that it would offend "our system of federalism" to "'imply' preemption based on the fact that a state tribunal may be called upon to interpret and apply a federal requirement in a suit seeking relief for conduct which violates that

[8] Plaintiffs assert that "the Court has refrained from finding implied preemption of private remedies for breach of substantive duties which do not differ from federal requirements." Pl. Br. 29. But they cite no case that supports the far-reaching principle that "allowing a non-federal remedy for violation of a federal requirement can not, by definition" result in implied preemption. *Id.* at 31. In fact, that proposition is squarely at odds with this Court's cases. See, *e.g.*, *Crosby*, 120 S. Ct. at 2298 ("[C]onflict is imminent when two separate remedies are brought to bear on the same activity * * *.") (citations and internal quotations omitted); *Pennsylvania* v. *Nelson*, 350 U.S. 497, 499-510 (1956) (Pennsylvania law criminalizing sedition against the United States is impliedly preempted by Smith Act, which proscribes the same conduct); *San Diego Bldg. Trades Council* v. *Garmon*, 359 U.S. 236, 246-247 (1959). See also U.S. Br. 20, 23-24.

requirement." Pl. Br. 31. But, contrary to plaintiffs' assumption, the states *cannot* provide a cause of action "for violation of FDCA requirements" (*id.* at 39; see also *id.* at 38, 40). As we explained in our opening brief (at 34-37), Congress chose *not* to make the FDCA enforceable in a private right of action and instead vested exclusive enforcement authority in the FDA. 21 U.S.C. § 337(a). This suit seeks to make an end run around that congressional judgment by allowing plaintiffs, in effect, to enforce the same FDCA requirements under the pretense of applying state law. The cases cited by plaintiffs (at 31) acknowledging the responsibility of state courts to enforce rather than disregard federal law are thus entirely beside the point.

In addition, plaintiffs overlook the more serious problem here, which is not the mere possibility of divergent interpretations. Instead, it is the fact that plaintiffs' "fraud on the FDA" claim amounts to a collateral attack on the FDA's clearance decision. To resolve plaintiffs' claim, a state judge or jury would have to guess whether the FDA relied on Buckman's disclosures and, if so, how the agency would have exercised its discretion if different disclosures had been made. And, to rule in plaintiffs' favor, a state judge or jury would have to nullify the FDA's decision that the devices at issue were properly on the market. As the Solicitor General has observed, "FDA's clearance decision is entitled to respect under the Supremacy Clause, and no State may provide a common law cause of action that fails to give effect to that decision." U.S. Br. 27. Plaintiffs have no response.[9]

3. Plaintiffs rely heavily (Br. 30, 32-34) on *Silkwood* v. *Kerr-McGee Corp.*, 464 U.S. 238 (1984), and *Miree* v. *DeKalb County*,

[9] Plaintiffs suggest that their collateral attack on the FDA's decision does not conflict with any federal interest because their subjective motivation is "recovery of damages for the injuries sustained by them, and not * * * regulatory compliance as an end in itself." Pl. Br. 34 n.12; see also *id.* at 35-36. But as this Court has frequently observed, "[t]he obligation to pay compensation" is "a potent method of governing conduct and controlling policy." *Garmon*, 359 U.S. at 247. See U.S. Br. 24.

433 U.S. 25 (1977), but those cases are easily distinguishable. The Court's rejection of implied preemption in *Silkwood* turned largely on affirmative evidence — conspicuously absent here — that "Congress * * * intended to tolerate whatever tension there was" between the Nuclear Regulatory Commission's "exclusive authority to regulate safety matters" under the Atomic Energy Act and the availability of punitive damages awards under state tort law. 464 U.S. at 256. In particular, the Court interpreted the Price Anderson Act, which establishes an indemnification scheme for nuclear operators held liable under state tort law, as constituting affirmative evidence of Congress's acceptance of state tort actions. See *id.* at 251-256. There is nothing comparable in this case; indeed, 21 U.S.C. §§ 336 and 337 are strong evidence of a contrary congressional intent.

The relevance of *Miree* is even more mysterious. That case involved the narrow question whether federal common law or state law governed the right of passengers in a plane crash and others to bring suit as third party beneficiaries against the Georgia county that ran the airport under contracts with the FAA. 433 U.S. at 28-29. Noting that the resolution of this issue "raises no question concerning the liability of the United States or the responsibility of the United States under the contracts," the Court held that state law should control. The Court explained that the federal government's operations would not "be burdened or subjected to uncertainty by variant state-law interpretations regarding whether those with whom the United States contracts might be sued by third-party beneficiaries to the contracts." *Id.* at 30. Indeed, so slight was the federal interest that the United States waived its right to file a brief on the ground that its interests "would not be directly affected" by the outcome. *Id.* at 29-30.

Here, in contrast, plaintiffs' claim *does* raise a question directly implicating the exclusive responsibility of the federal government to enforce the MDA, including the consideration of submissions that regulated entities must make in federal regulatory proceedings and the enforcement actions, if any, that the FDA will take in response to alleged violations of agency disclosure requirements.

Moreover, unlike in *Miree*, plaintiffs' "fraud on the agency" claim "implicates an area of paramount federal concern" — namely, the "need of federal regulatory agencies to receive accurate information from entities they regulate" and, more generally, "the relationship between the federal government and the entities it regulates." U.S. Br. 18-19.

4. Unable to explain away the clear conflict with federal interests, plaintiffs next resort (at 33-34 & n.12) to the "presumption against preemption" to defeat implied preemption here. As both we (at 32 n.7) and the government (at 17-21) have explained, however, that presumption has no application in this case because plaintiffs' "fraud on the FDA" claim does not represent a traditional state remedy and because "the relationship between the federal government and the entities it regulates" — including what disclosures must be made to a federal agency in a federal proceeding — involve "an area where there has been a history of significant federal presence." *United States* v. *Locke*, 120 S. Ct. 1135, 1147 (2000). See also PLAC Br. 20-24. It is worth repeating that plaintiffs' state law claim would not even exist were it not for the existence of the federal regulatory scheme.

5. In our opening brief (at 40-45), we explained that plaintiffs' claim, if allowed to proceed, would substantially interfere with the operations of the federal government in a variety of ways, including by sapping agency resources and embroiling agency personnel in litigation and by adversely affecting the regulatory process. See also Medtronic Sofamor Danek Br. 19-24; MDMA Br. 13-20; PhRMA Br. 20-27; PLAC Br. 15-20. In addition, if allowed to proceed, "fraud on the agency" claims could easily be used to circumvent a wide variety of federal administrative decisions on the ground that they were the product of "fraud." The government agrees that a host of "undesirable practical consequences" would flow from a finding of no preemption in this case, including the real prospect of "highly intrusive inquiries into FDA's internal deliberations," "distort[ions]" in "the behavior of regulated entities," and a "real danger of making it more difficult for FDA to perform its central function of protecting the public

health." U.S. Br. 28-30.

Plaintiffs simply ignore most of these adverse consequences. The only problem they address (Pl. Br. 45-47) is embroiling agency personnel in litigation. In essence, plaintiffs suggest that the appropriate response to this problem is to bar discovery from FDA officials. Pl. Br. 46. But that would be manifestly unfair to litigants such as petitioner, whose liability under plaintiffs' theory turns on what agency personnel knew and what they would have done if other information had been provided. Moreover, as the government points out, it would also "increase the danger that the jury's decision would conflict with FDA's judgment concerning whether it was defrauded and, if so, what should be done," because a jury deprived of such evidence "could only speculate about the crucial issues in the case." U.S. Br. 29.

III. THE COURT SHOULD RECONSIDER THE "SPECIFICITY" GLOSS ON 21 U.S.C. § 360K(A)

If the Court rejects our arguments for express and implied preemption under current law, then it should take this opportunity to reconsider the conclusion — endorsed in *Medtronic* over the dissent of four Justices — that express preemption under the MDA is limited to "specific" requirements. Plaintiffs do not dispute that, as we have shown (Pet. 14-16, 19-25), and as the Sixth Circuit recently confirmed, "[t]he various courts of appeals that have confronted issues of preemption arising under the MDA have struggled mightily with [*Medtronic*'s] language in the effort to discern its holding." *Kemp*, slip op. 13. Nor do plaintiffs deny that the concept of "specificity" is inherently ambiguous; they make no attempt to show that the "specificity" gloss has any statutory support or can be reconciled with this Court's decisions rejecting this "utterly irrational loophole" in other express preemption settings.

Other than an appeal to *stare decisis*, plaintiffs' only response is to address an argument we never made. They urge this Court to reject our "*de facto* suggestion that the Court overrule the 'Identity of Requirements' holding in *Medtronic*." Pl. Br. 24 n.10. But we

have not suggested that the Court reconsider *this* aspect of *Medtronic*, which, unlike the "specificity" gloss, has support in the statutory text and has created no confusion in the lower courts.[10]

For the reasons stated above and in our opening brief, the federal disclosure requirements at issue in this case should satisfy any sensible interpretation of the "specificity" concept. But if the Court disagrees, then we urge it to revisit the question whether Section 360k(a) requires federal requirements to be "specific"(as opposed to being "counterpart," see 21 C.F.R. § 808.1(d)) before preemption may occur. See WLF Br. 21-25. *Stare decisis* should not prevent the Court from reconsidering a narrowly divided issue decided only four years ago that was premised upon a misunderstanding of past agency practice and that has proven to be completely unworkable. See *Hohn* v. *United States*, 524 U.S. 236, 251 (1998); *State Oil* v. *Khan*, 522 U.S. 3, 21-22 (1997); *Solorio* v. *United States*, 483 U.S. 435, 448 (1987).

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[10] The "identity of requirements" holding in *Medtronic* finds textual support in the phrase "different from, or in addition to" in 21 U.S.C. § 360k(a). In contrast, as the four dissenters in *Medtronic* observed, "[t]he statute makes no mention of a requirement of specificity" (518 U.S. at 512 (O'Connor, J.)). The "specificity" gloss would have to be based on the statutory phrase "with respect to a device." But the FDA itself acknowledged in its *Medtronic* brief that "the 'with respect to' clause suggests" that the state requirements covered by Section 360k(a) "may be * * * of *general* applicability." Nos. 95-754 and 95-886 U.S. Br. 18 (emphasis added). And, as explained in our opening brief (at 47-48), the FDA's *Medtronic* brief and its regulatory notices took the position that the federal GMP requirements — which are general in content and applicability — triggered preemption under Section 360k(a). Thus, deference to the FDA's views and past exemption practice should have led the majority to *reject* importing the notion of specificity into the statute.

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted.

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APPENDIX

21 U.S.C. § 360c(i):

(i) Substantial equivalence

(1)(A) For purposes of determinations of substantial equivalence under subsection (f) of this section and section 360j(l) of this title, the term "substantially equivalent" or "substantial equivalence" means, with respect to a device being compared to a predicate device, that the device has the same intended use as the predicate device and that the Secretary by order has found that the device —

> **(i)** has the same technological characteristics as the predicate device, or
>
> **(ii)** (I) has different technological characteristics and the information submitted that the device is substantially equivalent to the predicate device contains information, including appropriate clinical or scientific data if deemed necessary by the Secretary or a person accredited under section 360m of this title, that demonstrates that the device is as safe and effective as a legally marketed device, and (II) does not raise different questions of safety and effectiveness than the predicate device.

(B) For purposes of subparagraph (A), the term "different technological characteristics" means, with respect to a device being compared to a predicate device, that there is a significant change in the materials, design, energy source, or other features of the device from those of the predicate device.

(C) To facilitate reviews of reports submitted to the Secretary under section 360(k) of this title, the Secretary shall consider the extent to which reliance on postmarket controls may expedite the classification of devices under subsection (f)(1) of this section.

(D) Whenever the Secretary requests information to demonstrate that devices with differing technological

characteristics are substantially equivalent, the Secretary shall only request information that is necessary to making substantial equivalence determinations. In making such request, the Secretary shall consider the least burdensome means of demonstrating substantial equivalence and request information accordingly.

(E)(i) Any determination by the Secretary of the intended use of a device shall be based upon the proposed labeling submitted in a report for the device under section 360(k) of this title. However, when determining that a device can be found substantially equivalent to a legally marketed device, the director of the organizational unit responsible for regulating devices (in this subparagraph referred to as the "Director") may require a statement in labeling that provides appropriate information regarding a use of the device not identified in the proposed labeling if, after providing an opportunity for consultation with the person who submitted such report, the Director determines and states in writing —

(I) that there is a reasonable likelihood that the device will be used for an intended use not identified in the proposed labeling for the device; and

(II) that such use could cause harm.

(ii) Such determination shall —

(I) be provided to the person who submitted the report within 10 days from the date of the notification of the Director's concerns regarding the proposed labeling;

(II) specify the limitations on the use of the device not included in the proposed labeling; and

(III) find the device substantially equivalent if the requirements of subparagraph (A) are met and if the labeling for such device conforms to the limitations

specified in subclause (II).

(iii) The responsibilities of the Director under this subparagraph may not be delegated.

(iv) This subparagraph has no legal effect after the expiration of the five-year period beginning on November 21, 1997.

(F) Not later than 270 days after November 21, 1997, the Secretary shall issue guidance specifying the general principles that the Secretary will consider in determining when a specific intended use of a device is not reasonably included within a general use of such device for purposes of a determination of substantial equivalence under subsection (f) of this section or section 360j(l) of this title.

(2) A device may not be found to be substantially equivalent to a predicate device that has been removed from the market at the initiative of the Secretary or that has been determined to be misbranded or adulterated by a judicial order.

(3)(A) As part of a submission under section 360(k) of this title respecting a device, the person required to file a premarket notification under such section shall provide an adequate summary of any information respecting safety and effectiveness or state that such information will be made available upon request by any person.

(B) Any summary under subparagraph (A) respecting a device shall contain detailed information regarding data concerning adverse health effects and shall be made available to the public by the Secretary within 30 days of the issuance of a determination that such device is substantially equivalent to another device.

21 C.F.R. § 801.4 (2000):

§ 801.4 Meaning of "intended uses."

The words "intended uses" or words of similar import in §§ 801.5, 801.119, and 801.122 refer to the objective intent of the persons legally responsible for the labeling of devices. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised. The intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer. If, for example, a packer, distributor, or seller intends an article for different uses than those intended by the person from whom he received the devices, such packer, distributor, or seller is required to supply adequate labeling in accordance with the new intended uses. But if a manufacturer knows, or has knowledge of facts that would give him notice that a device introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a device which accords with such other uses to which the article is to be put.

21 C.F.R. § 807.87 (2000):

§ 807.87 Information required in a premarket notification submission.

Each premarket notification submission shall contain the following information:

(a) The device name, including both the trade or proprietary name

and the common or usual name or classification name of the device.

(b) The establishment registration number, if applicable, of the owner or operator submitting the premarket notification submission.

(c) The class in which the device has been put under section 513 of the act and, if known, its appropriate panel; or, if the owner or operator determines that the device has not been classified under such section, a statement of that determination and the basis for the person's determination that the device is not so classified.

(d) Action taken by the person required to register to comply with the requirements of the act under section 514 for performance standards.

(e) Proposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use. Where applicable, photographs or engineering drawings should be supplied.

(f) A statement indicating the device is similar to and/or different from other products of comparable type in commercial distribution, accompanied by data to support the statement. This information may include an identification of similar products, materials, design considerations, energy expected to be used or delivered by the device, and a description of the operational principles of the device.

(g) Where a person required to register intends to introduce into commercial distribution a device that has undergone a significant change or modification that could significantly affect the safety or effectiveness of the device, or the device is to be marketed for a new or different indication for use, the premarket notification submission must include appropriate supporting data to show that the manufacturer has considered what consequences and effects the change or modification or new use might have on the safety

and effectiveness of the device.

(h) A 510(k) summary as described in § 807.92 or a 510(k) statement as described in § 807.93.

(i) A financial certification or disclosure statement or both, as required by part 54 of this chapter.

(j) For submissions claiming substantial equivalence to a device which has been classified into class III under section 513(b) of the act:

(1) Which was introduced or delivered for introduction into interstate commerce for commercial distribution before December 1, 1990; and

(2) For which no final regulation requiring premarket approval has been issued under section 515(b) of the act, a summary of the types of safety and effectiveness problems associated with the type of devices being compared and a citation to the information upon which the summary is based (class III summary). The 510(k) submitter shall also certify that a reasonable search of all information known or otherwise available about the class III device and other similar legally marketed devices has been conducted (class III certification), as described in § 807.94. This information does not refer to information that already has been submitted to the Food and Drug Administration (FDA) under section 519 of the act. FDA may require the submission of the adverse safety and effectiveness data described in the class III summary or citation.

(k) A statement that the submitter believes, to the best of his or her knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

(l) Any additional information regarding the device requested by the Commissioner that is necessary for the Commissioner to make

a finding as to whether or not the device is substantially equivalent to a device in commercial distribution. A request for additional information will advise the owner or operator that there is insufficient information contained in the original premarket notification submission for the Commissioner to make this determination and that the owner or operator may either submit the requested data or a new premarket notification containing the requested information at least 90 days before the owner or operator intends to market the device, or submit a premarket approval application in accordance with section 515 of the act. If the additional information is not submitted within 30 days following the date of the request, the Commissioner will consider the premarket notification to be withdrawn.

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No. 98-1768

In the Supreme Court of the United States

BUCKMAN COMPANY, PETITIONER

v.

PLAINTIFFS' LEGAL COMMITTEE

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE SUPPORTING PETITIONER

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QUESTION PRESENTED

Whether federal law preempts state-law tort claims alleging fraud on the Food and Drug Administration during the regulatory process for marketing clearance applicable to certain medical devices.

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In the Supreme Court of the United States

No. 98-1768

BUCKMAN COMPANY, PETITIONER

v.

PLAINTIFFS' LEGAL COMMITTEE

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE SUPPORTING PETITIONER

INTEREST OF THE UNITED STATES

This case presents the question whether federal law expressly or impliedly preempts state-law tort claims alleging fraud on the Food and Drug Administration (FDA) during the process of obtaining premarket clearance for certain medical devices under the Federal Food, Drug, and Cosmetic Act (FDCA). The United States has a substantial interest in the resolution of that issue. FDA is responsible for administering the premarket-clearance process for medical devices, and the decision in this case will affect that responsibility. In addition, FDA has issued regulations (21 C.F.R. 808.1) that interpret the FDCA's express preemption provision, 21 U.S.C. 360k(a). At the Court's invitation, the United States filed a brief as amicus curiae at the petition stage in this case, and that brief urged the Court to grant the petition for a writ of certiorari.

STATEMENT

Respondents are persons who claim that they suffered injuries when their physicians implanted orthopedic bone screws into the pedicles of their spines. They allege that

Buckman Company (petitioner) fraudulently obtained clearance from FDA for another company, AcroMed, to market the pedicle screws, and they seek to hold petitioner liable under state law for its alleged role in causing their injuries. The district court granted petitioner's motion to dismiss, holding that respondents' fraud-on-the-FDA claims are preempted by federal law. The court of appeals reversed, holding that such claims are not preempted.

1. a. The FDCA, 21 U.S.C. 301 *et seq.*, regulates food, drugs, cosmetics, and medical devices, and authorizes FDA to enforce its requirements. The Medical Device Amendments of 1976 (MDA), Pub. L. No. 94-295, 90 Stat. 539, supplemented the FDCA's medical device requirements. The MDA classifies medical devices into three classes based on the risk they pose to the public and the controls necessary to provide a reasonable assurance of a device's safety and effectiveness. 21 U.S.C. 360c(a) (1994 & Supp. IV 1998). Class I devices present no unreasonable risk of illness or injury and are subject to regulation through "general controls." 21 U.S.C. 360c(a)(1)(A). Class II devices are potentially more harmful. Such devices are also subject to general controls, but FDA in addition has authority to require that such devices comply with other requirements known as "special controls." 21 U.S.C. 360c(a)(1)(B). Class III devices present "a potential unreasonable risk of illness or injury." 21 U.S.C. 360c(a)(1)(C)(ii)(II). All post-1976 devices are initially deemed Class III devices. 21 U.S.C. 360c(f)(1).

In general, before a Class III device may be introduced into the market, a manufacturer must obtain a "premarket approval" (PMA) from FDA. 21 U.S.C. 360c(a)(1)(C), 360e(a). To obtain a PMA, the manufacturer must submit information to FDA that provides reasonable assurance that the device is safe and effective for its intended use. 21 U.S.C. 360c(a)(1)(C), 360e(a), (c) and (d) (1994 & Supp. IV 1998); 21 C.F.R. Pt. 814. A "grandfathering" provision permits Class III devices that were on the market before the

MDA's enactment to remain on the market until FDA initiates and completes a rulemaking requiring the submission of a PMA. 21 U.S.C. 360e(b)(1)(A). In the interest of fairness and to prevent "grandfathered" manufacturers from monopolizing the market, Congress also permitted other manufacturers to distribute similar devices by showing through a premarket notification process that they are "substantially equivalent" to grandfathered devices. 21 U.S.C. 360e(b)(1)(B). That premarket notification process is known as the "Section 510(k) process," referring to the section of the FDCA codified at 21 U.S.C. 360(k). A device is "substantially equivalent" to a grandfathered device only if, *inter alia*, it has the same "intended use" as that device. 21 U.S.C. 360c(i)(1)(A) (1994 & Supp. IV 1998).

b. FDA regulations set forth the information that an applicant must supply in order to obtain clearance under Section 510(k). 21 C.F.R. 807.87. The manufacturer must furnish, *inter alia*, "[p]roposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use," 21 C.F.R. 807.87(e), "[a] statement indicating the device is similar to and/or different from other products of comparable type in commercial distribution, accompanied by data to support the statement," 21 C.F.R. 807.87(f), and "[a]ny additional information regarding the device requested by [FDA] that is necessary for [FDA] to make a finding as to whether or not the device is substantially equivalent to a device in commercial distribution," 21 C.F.R. 807.87(*l*). The regulations also require each person submitting a premarket notification to state that, "to the best of his or her knowledge," all "data and information" are "truthful and accurate" and that "no material fact has been omitted." 21 C.F.R. 807.87(k).

Federal law generally prohibits persons from making false or fraudulent statements in submissions to federal agencies, see 18 U.S.C. 1001 (1994 & Supp. IV 1998), and the FDCA specifically prohibits, "[w]ith respect to any device, the

submission of any report that is required by or under this chapter that is false or misleading in any material respect." 21 U.S.C. 331(q)(2). FDA has authority to investigate suspected fraud by a person seeking market clearance, 21 U.S.C. 372; 21 C.F.R. 5.35, and may pursue a wide range of remedies and sanctions if it uncovers such fraud, see 21 U.S.C. 332 (injunctive relief); 21 U.S.C. 333(f)(1)(A) (civil money penalties); 21 U.S.C. 334(a)(2)(D) (seizure of the device); 21 U.S.C. 333(a) (criminal prosecution). FDA has established an enforcement policy concerning fraud in premarket submissions that details the kinds of remedies it is likely to pursue. See 56 Fed. Reg. 46,191, 46,199-46,200 (1991). Any citizen who believes that a submitter has committed fraud may petition FDA to take administrative action. 21 C.F.R. 10.30. All lawsuits to enforce the Act's provisions, however, "shall be by and in the name of the United States." 21 U.S.C. 337(a).

c. The MDA contains an express preemption provision, 21 U.S.C. 360k(a), which provides:

> (a) General rule
>
> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

Subsection (b) authorizes the Secretary to grant exemptions to the preemption provision in certain circumstances. FDA has issued regulations that interpret the scope of Section 360k(a). Under FDA's interpretation, State or local requirements are preempted only when FDA "has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act." 21 C.F.R. 808.1(d).

This Court addressed Section 360k's preemptive effect in *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996). The *Medtronic* plaintiffs filed state common law tort actions for injuries caused by a pacemaker that FDA had cleared for distribution under Section 510(k). Plaintiffs asserted causes of action based on defective design, negligent manufacturing, and negligent labeling. The Court first held that Medtronic's compliance with the Section 510(k) premarket clearance process did not preempt plaintiffs' defective design claims, because FDA's clearance did not "require" the pacemaker "to take any particular form for any particular reason." *Id.* at 493; accord *id.* at 513 (O'Connor, J. concurring in part and dissenting in part). The Court next held that Section 360k did not preempt state-law claims in which the duty of care paralleled FDA requirements. *Id.* at 495; accord *id.* at 513 (O'Connor, J., concurring in part and dissenting in part). The Court explained that common law duties that "parallel" federal requirements are not "different from, or in addition to," the federal requirements. *Ibid.*

Finally, the Court held that Section 360k did not preempt plaintiffs' state-law claims based on negligent manufacturing and labeling. 518 U.S. at 497-502. The Court recognized that FDA regulations impose general manufacturing and labeling requirements. The Court noted, however, that under Section 360k, "federal requirements must be 'applicable to the device' in question, and, according to [FDA] regulations [construing Section 360k], pre-empt state law only if they are 'specific counterpart regulations' or 'specific' to a 'particular device.'" *Id.* at 500. The Court therefore concluded that the "entirely generic" federal manufacturing and labeling requirements did not preempt the *Medtronic* plaintiffs' negligent manufacturing and labeling claims. *Id.* at 501.

2. a. Petitioner, a regulatory consultant, was retained by the AcroMed Corporation to act as its liaison to FDA. Pet. App. 4a. In September 1984, petitioner, on behalf of AcroMed, made a Section 510(k) submission to FDA to obtain marketing clearance for an orthopedic bone screw device known as the Variable Screw Placement (VSP) Spinal Plate Fixation System. *Ibid.* Petitioner's submission stated that AcroMed intended to market the device for use in spinal surgery. *Id.* at 4a-5a. FDA denied the request, finding that the VSP device was a Class III device and was not substantially equivalent to any predicate device marketed before the MDA's enactment. *Id.* at 5a. In September 1985, petitioner filed a second submission for marketing clearance, again stating that the device was intended for use in spinal surgery. *Ibid.* FDA denied the submission on the same ground. *Ibid.*

In December 1985, petitioner and AcroMed made a different attempt to obtain marketing clearance. Pet. App. 5a. They split the VSP device into its two component parts, which they called "nested bone plates" and "cancellous bone screws," and they filed separate Section 510(k) submissions for each component. *Ibid.* Those submissions stated that the devices were intended to be used in long bones of the arms and legs. *Ibid.* In responding to an FDA request for additional information about the devices' intended use, petitioner stated that they "are intended for use in appropriate fractures of long bones of both the upper and lower extremity and such other flat bones (as in the fractured pelvis)." J.A. 16. In February 1986, FDA granted marketing clearance for AcroMed's bone plates and screws for that stated purpose. Pet. App. 5a.

b. Respondents are plaintiffs who filed lawsuits alleging that they were injured when their doctors inserted the assembled VSP device into their spines. Pet. App. 1a. More than 2300 individual lawsuits were brought against multiple defendants, and those suits were consolidated for pre-trial

proceedings in the Eastern District of Pennsylvania pursuant to the multi-district litigation statute, 28 U.S.C. 1407 (1994 & Supp. IV 1998). Pet. App. 1a. The only count against petitioner is one that respondents call "fraud on the FDA." *Id.* at 5a. That count asserts that petitioner intentionally and falsely represented to FDA that the devices for which it sought clearance were "intended for use" in the long bones, when, in fact, the devices were "intended exclusively for use in the spine." J.A. 15-16. Respondents further allege that FDA did not know that the devices were intended exclusively for use in the spine, and that if petitioner had not made false statements about their intended use, FDA would not have cleared the devices for marketing, the devices would not have been sold, and respondents would not have been injured. J.A. 21. Respondents' claim does not depend on any allegation that the device itself was defective under state law or had been manufactured or labeled in a manner that was negligent or illegal under state law.

c. The district court dismissed the fraud-on-the-FDA claims on the ground that they were expressly preempted under 21 U.S.C. 360k. Pet. App. 53a. The district court reasoned that the MDA "does not permit courts to 'perform the same function initially entrusted to the FDA,'" *id* at 49a, and that FDA is in the "best position" to decide whether a manufacturer has "withheld material information from the agency and, if so, [to determine] the appropriate sanction," *id.* at 50a. After this Court decided *Medtronic*, respondents asked the district court to reinstate their fraud-on-the-FDA claims. *Id.* at 7a. The district court concluded that *Medtronic* foreclosed a finding of express preemption. *Id.* at 40a. It nevertheless refused to reinstate respondents' claims on the ground that they constituted an impermissible attempt to assert a private right of action for a violation of the MDA. *Id.* at 36a-40a.

3. A divided panel of the court of appeals reversed. Pet. App. 1a-32a. The court first held that respondents' fraud-on-

the-FDA claims are not expressly preempted, because there is neither a "federal 'requirement' 'applicable to the device' at issue," nor "a state 'requirement' 'with respect to' that device." *Id.* at 13a. The court further held that the "state common law relied upon [by respondents] does not impose any obligation on [petitioner] inconsistent with federal law," because "18 U.S.C. § 1001 makes it a crime to make a fraudulent statement to a federal agency and 21 C.F.R. § 807.87(j) requires every pre-market notification to contain a statement that the information contained therein is believed to be truthful." *Ibid.* The court of appeals also rejected the district court's conclusion that fraud-on-the-FDA claims constitute an impermissible attempt to obtain a private right of action for violations of the MDA. *Id.* at 13a-17a. The court concluded that such reasoning is inconsistent with *Medtronic*. *Id.* at 16a.

The court of appeals also held that respondents' fraud-on-the-FDA claims are not impliedly preempted. Pet. App. 18a. The court saw "no inconsistency between the FDA having the exclusive prerogative of bringing actions to enforce the FDCA" and "common law fraudulent misrepresentation claims." *Ibid.* Finally, the court rejected petitioner's contention that a statement of intended use refers to the use for which an applicant seeks market clearance. *Id.* at 22a-24a. The court held that a statement of intended use refers to an applicant's marketing intentions. *Id.* at 22a-23a. The court therefore concluded that, if AcroMed intended at the time of the application to market its device solely for use in the spine, petitioner's statement that the device was intended for use in the long bones would have constituted a material misrepresentation. *Id.* at 23a-24a.

Judge Cowen dissented. Pet. App. 25a-32a. Judge Cowen concluded that fraud-on-the-FDA claims conflict with federal law because they "greatly distort the penalty scheme established by the statute." *Id.* at 28a. In particular, the "penalties attached to a violation of the FDA's regulations will often be substantially increased, and enforcement of violations will no longer be controlled by the FDA's prosecutorial discretion." *Ibid.* Judge Cowen also concluded that fraud-on-the-FDA claims conflict with federal law because they permit juries to impose "[m]assive liability" when FDA "would not find any misconduct." *Id.* at 31a.

SUMMARY OF ARGUMENT

I. Respondents' fraud-on-the-FDA claims are not expressly preempted by FDA's Section 510(k) disclosure requirements. Under *Medtronic*, express preemption occurs only when (1) the federal requirement is specific, and (2) the counterpart state requirement is different from, or in addition to, that specific federal requirement. Neither of those prerequisites for express preemption is present here.

First, FDA's Section 510(k) disclosure requirements are not specific. They are stated in general terms, and they apply to all devices that must undergo the Section 510(k) clearance process, not just pedicle screw devices. Second, respondents' common law theory of liability does not impose a duty that is different from, or in addition to, the applicable federal requirements. Federal law requires a manufacturer to truthfully disclose a device's intended use in its submission for Section 510(k) clearance. Respondents' claim that petitioner falsely represented to FDA that its devices were intended for use in the long bones, when, in fact, they were intended exclusively for use in the spine, does not impose any requirement that is different from an applicable federal requirement.

II. Respondents' fraud-on-the-FDA claims nonetheless are impliedly preempted by federal law. When Congress legislates in a field of traditional state concern, there is a presumption against preemption. That presumption applied to the defective design, negligent manufacturing, and failure to warn claims at issue in *Medtronic*. Respondents' claims, however, focus on an entity's obligations to truthfully dis-

close information to a federal regulatory agency. That field is not one that States have traditionally occupied; instead, it is one of preeminent federal concern. Under this Court's cases, when state law intrudes on an area of preeminent federal concern, the presumption against preemption disappears, and the danger of a fatal conflict significantly increases.

Applying the preemption analysis that is appropriate when state law intrudes on an area of preeminent federal concern, respondents' fraud-on-the-FDA claims conflict with federal law. In particular, they conflict with the important federal interest in permitting FDA to decide for itself whether it has been defrauded, and, if so, what sanction is appropriate. If a State attempted to establish its own administrative agency to monitor fraud on the FDA, and devised its own set of sanctions for punishing such fraud, the conflict between that system and the federal interest in uniform enforcement would be apparent. That conflict is not lessened simply because the state scheme for regulating fraud on the FDA takes the form of a common law cause of action.

Respondents' fraud-on-the-FDA claims also conflict with FDA's decision to grant market clearance for AcroMed's pedicle screw devices. Respondents' claims proceed on the assumption that AcroMed should not have received market clearance for its pedicle screws from FDA, and that respondents should receive damages as if the marketing of the pedicle screws cleared by FDA was unlawful under the FDCA. Those assumptions directly conflict with FDA's decision clearing the devices for marketing under the FDCA.

Fraud-on-the-FDA claims also invite highly intrusive discovery concerning federal agency officials' states of mind and the courses of action that agency decisionmakers might have taken under various hypothetical scenarios. Such claims therefore pose a real danger of diverting FDA's resources from the important health mission that Congress

has assigned to it and of distorting FDA's internal decision-making process.

ARGUMENT

I. RESPONDENTS' FRAUD-ON-THE-FDA CLAIMS ARE NOT EXPRESSLY PREEMPTED

Petitioner contends (Pet. 26-27) that respondents' fraud-on-the-FDA claims are expressly preempted. In particular, petitioner argues that the federal requirement that an applicant for Section 510(k) marketing clearance submit information concerning a device's "intended use" preempts respondents' fraud-on-the-FDA claims. Under the MDA, however, express preemption occurs only when there is (1) a federal "requirement applicable to the device," and (2) the state requirement is "is different from, or in addition to," that federal requirement. 21 U.S.C. 360k(a). Neither of those prerequisites for express preemption is present here.

A. FDA's Disclosure Requirements Are Not Specific

In *Medtronic*, the Court held that federal "requirement[s]" are "applicable to the device" within the meaning of the MDA's express preemption provision only when they are "'applicable to the device' in question," 518 U.S. at 500, and, in accordance with FDA regulations, only when they are "'specific counterpart regulations' or 'specific' to a 'particular device,'" *ibid.* (quoting 21 C.F.R. 808.1(d)). Federal requirements therefore can have preemptive force under Section 360k(a) when "the Federal Government has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers." *Id.* at 501. Federal requirements do not have a preemptive effect under Section 360k(a), however, when they "reflect important but entirely generic concerns about device regula-

tion generally." *Id.* at 501-502; see also *id.* at 506-507 (Breyer, J., concurring in part and concurring in the judgment).

Medtronic establishes a sensible and administrable line for determining the kind of federal requirements that can have preemptive force under Section 360k(a). For example, FDA's requirements concerning hearing aids (21 C.F.R. 801.420, 801.421), cables and leads (21 C.F.R. 898), impact-resistant lenses (21 C.F.R. 801.410), and devices containing natural rubber (21 C.F.R. 801.437) preempt counterpart state requirements that are different from, or in addition to, those requirements. Those federal requirements are stated with specificity and apply to a specific device or set of devices. In contrast, as the Court explained in *Medtronic*, FDA's general manufacturing and labeling requirements do not have preemptive force. 518 U.S. at 501. Those requirements are stated at a high level of generality and apply to all devices.

Under the interpretation of the express preemption provision adopted in *Medtronic*, the requirement that an applicant submit information concerning a device's "intended use" does not have preemptive force. That requirement is stated in general terms, and it applies to all devices that must undergo the Section 510k clearance process, not just pedicle screw devices. See 21 C.F.R. 807.87(e). Thus, like the general manufacturing and labeling requirements at issue in *Medtronic*, the statement of intended use required of applicants in the Section 510k process is not a "'specific counterpart regulation[]' or 'specific' to a 'particular device.'" *Medtronic*, 518 U.S. at 500 (quoting 21 C.F.R. 808.1(d)). It is therefore not the kind of federal requirement that can have a preemptive effect under the MDA's express preemption provision.[1]

[1] As we explain in our amicus brief at the petition stage (at 10-11 n.4), Section 360k(a) does preempt a specific duty of care that is made applicable to a device through application in litigation of a State's common law of torts, if that requirement is different from, or in addition to, a specific requirement imposed by FDA. It does not follow from the fact that a general *state* tort duty may be preempted as applied in a particular case that the existence of general *federal* standards have preemptive force. The Court rejected that contention in *Medtronic*. 518 U.S. at 501-502; *id.* at 506-507 (Breyer, J., concurring in part and concurring in the judgment). Similarly, the fact that a device has been cleared by FDA through the Section 510(k) process does not mean that any general rules and duties governing that process have thereby been made "specific" to the device. At most, FDA would have determined only that any preexisting requirements governing the process (whether general or "specific") were satisfied. In any event, there is no indication in this case that FDA determined when it cleared the device under Section 510(k) that petitioner and AcroMed had satisfied all applicable duties of disclosure.

B. Respondents' Fraud-On-The-FDA Claims Parallel Federal Requirements

Even if the general duty to provide information to FDA about a product's "intended use" were the kind of federal requirement that could have a preemptive effect under Section 360k(a), respondents' fraud-on-the-FDA claims would still not be expressly preempted. As construed in *Medtronic*, Section 360k does not deny a State "the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements." 518 U.S. at 495. Such common law duties are not "different from, or in addition to," federal requirements within the meaning of Section 360k. *Ibid.*

Respondents' sample complaint includes allegations that petitioner committed common law fraud when it falsely informed FDA that AcroMed's devices were intended for use in long bones when, in fact, they were intended exclusively for use in the spine. Pet. App. 8a-9a; J.A. 15-16. Since federal law requires a manufacturer to truthfully disclose a device's intended use in its submission for Section 510(k) clearance (see 21 U.S.C. 331(q)(2); 18 U.S.C. 1001; 21

C.F.R. 807.87(e); 21 C.F.R. 807.87(k)), respondents' common law fraud theory parallels the applicable federal requirements. It is therefore not "different from, or in addition to," the applicable federal requirements within the meaning of Section 360k(a).

Petitioner argues (Pet. 27; Reply Br. Pet. Stage 9-10) that respondents' common law theory imposes a requirement that is different from the applicable federal requirement because, under federal law, "intended use" refers to the use set forth in the labeling, while respondents' common law theory equates intended use with a manufacturer's subjectively desired off-label uses. Petitioner's contention misreads both the applicable federal standards and the allegations in respondents' complaint.

Under FDA's regulations, the "intended use" of a medical device is defined by the "objective intent of the persons legally responsible for the labeling of [the] device[]," and objective intent "is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article." 21 C.F.R. 801.4. Because objective intent is determined in part by reference to a manufacturer's "expressions," a device's "labeling" is relevant in determining a device's intended use. 21 C.F.R. 801.4. But a device's labeling is not the exclusive source for determining intended use. Also relevant are, *inter alia*: (1) "advertising matter," (2) a manufacturer's "oral or written statements," (3) the manufacturer's "knowledge" that a product is "offered and used for a purpose for which it is neither labeled nor advertised," and (4) the manufacturer's "knowledge" of facts that would give him "notice" that a product "is to be used" for purposes other than those for which the manufacturer offered it. 21 C.F.R. 801.4. See also 21 C.F.R. 801.5 (discussing adequate directions for use of a device for its intended use).

Thus, when FDA seeks from an applicant a statement of a device's intended use, it is not simply asking for the use that

will appear on the labeling. It is asking for the intended use that will be revealed by all the manufacturer's "expressions" and "the circumstances surrounding" the device's "distribution." 21 C.F.R. 801.4. Under the regulations, a manufacturer is not required to disclose every foreseeable use of a device that it secretly desires. Physicians often use medical devices for purposes that are not identified in the labeling, and manufacturers may seek Section 510(k) clearance for the use identified in the labeling without setting forth every possible off-label use to which the device might be put after it reaches the market. But whatever may be the full scope of a manufacturer's duty to disclose possible uses of the device beyond those stated in the labeling the manufacturer has submitted, when, at the time of the application, a manufacturer plans to promote and distribute a device exclusively for one use, it must disclose to FDA that intended use. A statement to FDA that the device has a different intended use would be false and misleading. The intended use stated in the premarket notification must be a bona fide use, it cannot be a pretext calculated to clear the device for distribution for other uses.[2]

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[2] That conclusion is not affected by the 1997 amendments to the FDCA. Those amendments were not in effect at the time of petitioner's alleged misconduct. In any event, the amendments do not alter the analysis for devices subject to the Section 510(k) process after they were enacted. Under 21 U.S.C. 360c(i)(1)(A), as amended in 1990, a device can be found to be substantially equivalent to a pre-1976 device only if it "has the same intended use as the predicate device." The 1997 amendments provide only that (for a period of five years), in making a "substantial equivalence" determination, FDA's determination concerning a device's "intended use * * * shall be based upon the proposed labeling." 21 U.S.C. 360c(i)(1)(E)(i) (Supp. IV 1998). That provision does not relieve manufacturers of their obligation under 21 C.F.R. 807.87(e), 807.87(k) and 21 U.S.C. 331(q)(2) to truthfully inform FDA of a device's "intended use" as that term is defined in FDA's "intended use" regulation, 21 C.F.R. 801.4. The manufacturer must continue to furnish proposed labeling that accurately reflects the device's intended use, and FDA then determines

Respondents' sample complaint includes allegations that petitioner engaged in just such misleading conduct. Respondents do not claim that AcroMed intended to market its devices for use in the long bones, but secretly hoped that they would be used in spinal surgery as well. Rather, respondents claim that, while petitioner represented to FDA in its Section 510(k) submission that AcroMed's devices were intended to be used in the long bones, in fact, AcroMed planned to promote and distribute the devices exclusively for use in the spine. J.A. 15-16. That common law theory of liability does not rest on the imposition of a duty that is "different from" or "in addition to" federal requirements. Instead, that common law theory is consistent with the duties imposed by applicable federal requirements. It is therefore not expressly preempted.

II. RESPONDENTS' FRAUD-ON-THE-FDA CLAIMS ARE IMPLIEDLY PREEMPTED

The absence of express preemption, however, does not exhaust the preemption inquiry. An express preemption provision "does not bar the ordinary working of conflict pre-

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substantial equivalence based on the proposed labeling. The amendments also authorize FDA to require a statement in a device's labeling concerning "a use of the device not identified in the labeling" if FDA determines "that there is a reasonable likelihood that the device will be used for an intended use not identified in the proposed labeling" and "such use could cause harm." 21 U.S.C. 360c(i)(1)(E)(i)(I) and (II) (Supp IV 1998). That statutory authority confirms that a device's intended use may be determined from evidence other than a device's proposed labeling and that FDA is required to confine its inquiry to the intended use identified in the proposed labeling only when it makes a substantial equivalence determination. That statutory authority concerning other potentially harmful intended uses also underscores why a manufacturer seeking Section 510(k) clearance for a device must disclose all intended uses of the device, not merely those set forth in whatever proposed labeling the manufacturer chooses to submit in the Section 510(k) clearance process.

emption principles." *Geier* v. *American Honda Motor Co.*, 120 S. Ct. 1913, 1919 (2000). Those principles preclude respondents' fraud-on-the-FDA claims.

A. Fraud-On-The-FDA Claims Intrude On An Area Of Preeminent Federal Concern, And Are Therefore Subject To A More Stringent Conflict Preemption Analysis

1. When Congress legislates "in a field which the States have traditionally occupied," preemption analysis begins "with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Medtronic*, 518 U.S. at 485. That assumption "is consistent with both federalism concerns and the historic primacy of state regulation of matters of health and safety." *Ibid.* The *Medtronic* plaintiffs' claims of defective design, negligent manufacturing, and negligent failure to warn all implicated core areas of traditional state concern. The Court therefore began its analysis in *Medtronic* with a "presumption" that Congress did not intend to preempt those claims. *Ibid.*

The situation here is fundamentally different. Respondents' fraud-on-the-FDA claims do not depend on any showing that the device had a defective design, was negligently manufactured, or did not bear adequate warnings under state law. Pet. App. 8a-9a. Instead, respondents simply contend that, but for petitioner's alleged misrepresentations to FDA, the agency would not have cleared the device for marketing, the device would not have been marketed, and they would not have been injured. *Ibid.* Respondents' claim therefore does not focus on the device itself, on the manner in which it was designed, produced, and distributed, or on a State's legitimate interest in those subjects. It focuses,

rather, on the relationship between the federal government and the entities it regulates.

The field involving an individual's obligations to the federal government, and, more particularly, an individual's obligation to provide accurate information to a federal regulatory agency, is not one "which the States have traditionally occupied." *Medtronic*, 518 U.S. at 485. Unlike the traditional common law torts at issue in *Medtronic*, the newly fashioned state-law tort of committing fraud on a federal regulatory agency has no existence that is independent of the federal statutes that establish federal regulatory agencies and require regulated entities to make certain disclosures to those federal agencies. In this case, for example, a holding that fraud-on-the-FDA claims are preempted would not eliminate any claim that existed under state law before the MDA was enacted. Conversely, the field involving an individual's obligation to provide accurate information to a federal regulatory agency is one in which there is an overriding and longstanding federal interest. If federal regulatory agencies are to perform the important functions assigned to them by Congress, they must have the ability to decide, free from hindrances imposed by state law, how best to obtain the information they need and how to sanction those who fail to provide such information.

In enacting the 1934 amendment to 18 U.S.C. 1001, Congress recognized the paramount need of federal regulatory agencies to receive accurate information from entities they regulate. The 1918 version of Section 1001 had prohibited false statements to government officials made for the purpose of cheating the government out of property or money. That restricted scope "became a serious problem with the advent of the New Deal programs in the 1930s." *United States* v. *Yermian*, 468 U.S. 63, 80 (1984) (Rehnquist, J., dissenting). Because the new regulatory agencies relied heavily on the reports filed by regulated entities to ensure compliance, the filing of false reports could readily defeat the

agency's regulatory objectives. *United States* v. *Gilliland*, 312 U.S. 86, 92-93 (1941). To address that concern, Congress amended Section 1001 to prohibit the making of any false statement or the filing of any false writing or document on any matter within the jurisdiction of any department or agency of the United States. *Ibid.* That amendment confirms the importance that federal law places on a regulatory agency's ability to obtain accurate information from those it regulates.

2. Because respondents' fraud-on-the-FDA claims implicate an area of paramount federal interest, they are subject to a more stringent conflict preemption analysis. Under this Court's cases, when state law implicates an area of preeminent federal concern, the presumption against preemption disappears and the likelihood of a fatal conflict between state and federal law significantly increases.

For example, in *Boyle* v. *United Techs. Corp.*, 487 U.S. 500 (1988), the Court noted that, while "[i]n most fields of activity," the Court has "refused to find federal pre-emption of state law in the absence of either a clear statutory prescription * * * or a direct conflict between federal and state law," in areas involving "unique federal interests", the Court has more readily determined that state law is pre-empted. *Id.* at 504. The Court explained that the presence of a "unique federal concern changes what would otherwise be a conflict that cannot produce pre-emption into one that can." *Id.* at 508. Applying that analysis, the Court held that design defect suits against government contractors implicate unique federal interests that require the displacement of state law. *Id.* at 511-512. In reaching that conclusion, the Court noted that such suits border on two areas that it had previously found to involve uniquely federal interests: the obligations and rights of the United States under its contracts, which are governed exclusively by federal law, and the civil liability of federal officers for actions taken in the course of their official duty, which in many contexts is con-

trolled by federal law. *Id.* at 505. Just as federal law presumptively defines the duties owed by federal employees and contractors to the federal government, so too here federal law presumptively defines the duties owed to the federal government by entities regulated by the federal government. Cf. *Hancock* v. *Train*, 426 U.S. 167, 178-179 (1976).

Moreover, in *Boyle*, the plaintiff sought to hold the manufacturer liable for injuries caused by a product that allegedly was defective—a field generally subject to state law—and that state law was displaced only to the extent necessary to give effect to the countervailing federal interests.[3] Here, by contrast, respondents' fraud-on-the-FDA count does not depend on any claim that the product itself was independently defective under state law or on any claim that the distribution of the product independently violated any duty owed under state law. The concerns about the displacement of state law in *Boyle* are therefore largely inapplicable here.

In *Pennsylvania* v. *Nelson*, 350 U.S. 497 (1956), the Court held that federal sedition laws preempt comparable state prohibitions. The Court reasoned that the federal sedition laws "touch a field in which the federal interest is so dominant that the federal system [must] be assumed to preclude enforcement of state laws on the same subject." *Id.* at 504. The Court further explained that "[s]edition against the United States is not a *local* offense. It is a crime against the *Nation.* * * * It is not only important but vital that such prosecutions should be exclusively within the control of the Federal Government." *Id.* at 505.

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[3] In fashioning the scope of the government-contractor defense to liability under state law in those circumstances, the Court in *Boyle* relied on the discretionary function exemption under the Federal Tort Claims Act, 28 U.S.C. 2680(a), which exempts the United States from liability for performing the discretionary function of selecting an appropriate design. The Court held that to subject a federal contractor to liability for a design that was selected by the federal agency would undermine that exemption. 487 U.S. at 511-512.

And, in *United States* v. *Locke*, 120 S. Ct. 1135, 1151-1152 (2000), the Court held that Coast Guard regulations concerning the reporting of marine casualties preempted a state regulation that imposed similar requirements. The Court reasoned that the "assumption" of non-preemption does not apply "in an area where there has been a history of significant federal presence," *id.* at 1147, that maritime commerce constitutes such an area, *id.* at 1148, and that, in an area of preeminent federal concern, even state laws that mirror federal requirements can conflict with the intent to create "a workable, uniform system," *id.* at 1151.

B. Fraud-On-The-FDA Claims Conflict With The Important Federal Interest In Permitting FDA To Decide For Itself Whether It Has Been Defrauded, And, If So, What Remedy To Seek

Applying the analysis that is appropriate in cases involving an area of preeminent federal concern, respondents fraud-on-the-FDA claims are preempted. The FDCA establishes a comprehensive scheme to regulate the information that an entity must submit to FDA, and respondents' fraud on the FDA claims conflict with the strong federal interest in uniform enforcement of that comprehensive scheme.

1. FDA has issued regulations that set forth the information that an applicant must supply in order to obtain clearance under Section 510(k). 21 C.F.R. 807.87. The manufacturer must furnish, *inter alia*, "[p]roposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use," 21 C.F.R. 807.87(e), "[a] statement indicating the device is similar to and/or different from other products of comparable type in commercial distribution, accompanied by data to support the statement," 21 C.R.F. 807.87(f), and "[a]ny additional information regarding the device requested by [FDA] that is necessary for [FDA] to make a finding as to whether or not the device is substantially equivalent to a device in com-

mercial distribution," 21 C.F.R. 807.87(*l*). FDA has issued guidance on how to supply the information required by its regulations. See *Premarket Notification 510(k): Regulatory Requirements for Medical Devices, http://www.fda.gov /cdrh/manual/510kprt1.html.* FDA's regulations also require each person submitting a premarket notification to state that, "to the best of his or her knowledge," all "data and information" are "truthful and accurate" and that "no material fact has been omitted," 21 C.F.R. 807.87(k), and the FDCA specifically prohibits, "[w]ith respect to any device, the submission of any report that is required by or under this chapter that is false or misleading in any material respect," 21 U.S.C. 331(q)(2).

The FDCA also contains a comprehensive scheme for enforcing those obligations. FDA has authority to investigate suspected fraud by a person seeking market clearance, 21 U.S.C. 372; 21 C.F.R. 5.35, and may pursue a variety of remedies and sanctions if it uncovers such fraud, including injunctive relief, 21 U.S.C. 332, civil money penalties, 21 U.S.C. 333(f)(1)(A), seizure of the device, 21 U.S.C. 334(a)(2)(D), and criminal prosecution, 21 U.S.C. 333 (a), 18 U.S.C. 1001 (1994 & Supp. IV 1998). FDA has adopted an enforcement policy concerning fraud and untrue statements of material facts in premarket submissions. 56 Fed. Reg. 46,191, 46,199-46,200 (1991). Under that policy, when FDA finds that a submission contains fraudulent and unreliable data, it may withdraw clearance of a device cleared for marketing under Section 510(k) and seek voluntary corrective action from the submitter, such as removal of the persons involved in the wrongdoing from substantive responsibility for matters under FDA's jurisdiction. *Ibid.* Any citizen who believes that a submitter has committed fraud may petition FDA to take administrative action. 21 C.F.R. 10.30. But there is no private right of action to enforce the FDCA's prohibitions. *Medtronic*, 518 U.S. at 487. FDA and the United States have exclusive authority to determine

how the provisions of the Act should be enforced. See 21 U.S.C. 337(a).

2. Respondents' fraud-on-the-FDA claims conflict with that comprehensive federal scheme for regulating the information that a regulated entity must submit to FDA. In particular, they conflict with the strong federal interest in permitting FDA to decide for itself whether it has been defrauded, and, if so, what statutorily authorized remedy to seek. That conflict manifests itself in three ways.

First, fraud-on-the-FDA claims would permit juries in different States to reach judgments that differ from FDA's concerning whether an entity has actually committed fraud on the FDA. As Judge Cowen observed in his dissenting opinion in this case, juries could "impose massive liability," when FDA "would not find any misconduct." Pet. App. 31a. Even if juries in different States applied the same substantive standards as FDA, it would not eliminate that conflict. As this Court has explained, "[a] multiplicity of tribunals and a diversity of procedures are quite as apt to produce incompatible or conflicting adjudications as are different rules of substantive law." *Garner* v. *Teamsters*, 346 U.S. 485, 490-491 (1953).

Second, allowing fraud-on-the-FDA claims would "distort the penalty scheme established by the statute." Pet. App. 28a (Cowens, J., dissenting). While the FDCA contains a wide range of possible remedies for fraud on the FDA, neither compensatory relief nor punitive damages is among them. "[S]ince remedies form an ingredient of any integrated scheme of regulation, to allow the State to grant a remedy * * * which has been withheld from the [FDA], * * * accentuates the danger of conflict." *San Diego Bldg, Trades Council* v. *Garmon*, 359 U.S. 236, 247 (1959); see also *Crosby* v. *National Foreign Trade Council*, 120 S. Ct. 2288, 2298 (2000) ("[C]onflict is imminent when two separate remedies are brought to bear on the same activity.")

Third, if common law fraud-on-the-FDA claims are permitted, it would interfere with FDA's discretion to decide which of the statutorily prescribed remedies, if any, to pursue. The FDCA allows FDA to pursue the remedies that, in FDA's judgment, best fit the violation and the overall purposes of the Act. See *Heckler* v. *Chaney*, 470 U.S. 821, 831 (1985). For example, FDA may decide in a particular case in which fraud has been identified that the established health benefits of the device concerned counsel against removing the device from the market or imposing a severe penalty, and that removing the persons involved in the wrongdoing from responsibility for submissions is a more appropriate sanction. If fraud-on-the-FDA claims may be brought, the juries in 50 States could substitute their judgments for FDA's as to the appropriate sanction. Since fraud on the FDA "is not a *local* offense," but an offense against the United States, it is "vital" that enforcement "should be exclusively within the control of the Federal Government." *Nelson*, 350 U.S. at 505.

3. Because there is a strong federal interest in permitting FDA to decide for itself whether it has been defrauded, and, if so, what sanction is appropriate, state regulation of fraud on the FDA is preempted. If a State attempted to establish its own administrative agency to monitor fraud on the FDA, and devised its own set of sanctions for punishing such fraud, the conflict between that system and the federal interest in uniform enforcement would be apparent. That sharp conflict is not lessened simply because the state scheme for regulating fraud on the FDA takes the form of a common law cause of action. See *Garmon*, 359 U.S. at 247 ("The obligation to pay compensation" is "a potent method of governing conduct and controlling policy."). On the contrary, permitting private prosecution of fraud on the FDA only exacerbates the conflict, since private parties have no obligation to take into account the public interest before filing suit. *Nelson*, 350 U.S. at 507-508.

C. Respondents' Fraud-On-The-FDA Claims Conflict With FDA's Market Clearance Decision

Respondents' fraud-on-the-FDA claims are preempted for another reason. They conflict with FDA's decision to grant market clearance for AcroMed's pedicle screw devices.

1. Under basic principles grounded in the Supremacy Clause, a federal administrative decision that has neither been rescinded by the agency nor set aside by a federal court in accordance with the procedures for review established by Congress has a preemptive effect. A State may not provide a common law cause of action that fails to give effect to such a decision. *Arkansas La. Gas Co* v. *Hall*, 453 U.S. 571 (1981) (*Arkla*); *Chicago & North Western Transp. Co.* v. *Kalo Brick & Tile Co.*, 450 U.S. 311 (1981).

Arkla and *Kalo Brick* illustrate the preemptive effect of federal administrative decisions on state common law causes of action. In *Arkla*, Hall contracted to sell natural gas to Arkla at a specified rate, but the contract provided that, if Arkla purchased natural gas from another party at a higher rate, Hall would be entitled to that rate. 453 U.S. at 573. Hall filed the agreed-upon rate with the Federal Power Commission, and the Commission authorized the sale of gas at that rate. *Id.* at 574. Some years later, Arkla purchased gas from another party at a higher rate, but did not inform Hall of that fact or increase its payments to Hall. When Hall learned of Arkla's higher payments to the other party, he filed a state court breach of contract action, and the Louisiana Supreme Court awarded as damages the difference between what Arkla paid Hall and what it paid to the third party. *Id.* at 574.

This Court reversed, holding that the state contract action was preempted by the Commission's approval of Hall's filed rate. *Arcla*, 453 U.S. at 578-579. The Court reasoned that the "filed rate doctrine" forbids a regulated entity to charge rates for its services other than those filed with the

appropriate federal regulatory agency, and that it would undermine the federal scheme to allow a state court to award as damages a rate never filed with the Commission and never found by the Commission to be reasonable. *Id.* at 578-579. The Louisiana Supreme Court's determination that the Commission would have approved the higher rate as reasonable had it known about the circumstances of the case did not eliminate the conflict, *id.* at 580-581, since "under the filed rate doctrine, the Commission alone is empowered to make that judgment, and until it has done so, no rate other than the one on file may be charged," *id.* at 581. By awarding damages based on an assumption about what the Commission might have done, the Louisiana Supreme Court had "usurped a function that Congress ha[d] assigned to a federal regulatory body." *Id.* at 582; see also *Nantahala Power & Light Co.* v. *Thornburg*, 476 U.S. 953, 963-964 (1986).

In *Kalo Brick*, the Interstate Commerce Commission approved a rail carrier's request to abandon service on a particular rail line. 450 U.S. at 314-315. Rather than seeking judicial review of the Commission's decision, a shipper who used that line asserted a common law tort action against the rail carrier for damages resulting from the abandonment of service. *Id.* at 315. The Court held that the common law tort action was preempted by the Commission's decision. *Id.* 324-327. The Court rejected the argument that the state tort remedy merely complemented the federal abandonment remedy. *Id.* at 324. The Court reasoned that the Act grants "exclusive discretion" to the Commission to decide whether a carrier should be permitted to abandon service on a line, and that it would be contrary to that feature of the Act "to permit litigation challenging the lawfulness of the carrier's actions to go forward when the Commission has expressly found them to be reasonable." *Id.* at 326.

2. Under the principles applied in *Arkla* and *Kalo Brick*, respondents' fraud-on-the FDA claims are preempted. FDA granted market clearance for AcroMed's pedicle screws, and

that decision has not been rescinded by FDA or set aside by a federal court in accordance with the procedures for judicial review established by Congress. Accordingly, under *Arkla* and *Kalo Brick*, FDA's clearance decision is entitled to respect under the Supremacy Clause, and no State may provide a common law cause of action that fails to give effect to that decision.

Respondents' fraud-on-the-FDA claims, however, fail to give effect to FDA's market clearance decision. Those claims proceed on the assumption that AcroMed should not have received market clearance for its pedicle screws from FDA, and that respondents should receive damages as if the marketing of the pedicle screws cleared by FDA was unlawful under the FDCA. C.A. App. A63. Those assumptions directly conflict with FDA's decision clearing the devices for marketing under the FDCA. Litigation "challenging the lawfulness" of petitioner's actions in obtaining market clearance for the devices under the FDCA cannot "go forward" when FDA has "expressly found" that the devices should be cleared for marketing under that Act. *Kalo Brick*, 450 U.S. at 326. Respondents' assertion that FDA would not have cleared the devices had it known that petitioner misrepresented their intended use, moreover, does nothing to avert the conflict. FDA "alone is empowered" to decide whether a device should be cleared for marketing under the FDCA, and, by seeking damages based on an assumption concerning what FDA "might have done," respondents seek to "usurp[] a function that Congress has assigned to a federal regulatory body." *Arkla*, 453 U.S. at 581-582.[4]

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[4] Respondents' claims do not conflict with FDA's 1998 decision to classify and reclassify pedicle screw spinal systems for certain uses as Class II devices. FDA's classification and reclassification decision occurred after the underlying events at issue here (see Pet. App. 5a), and it was not intended to legitimize conduct that was unlawful at the time it occurred. 63 Fed. Reg. 40,025, 40,037-40,038 (1998). We also note that FDA classified and reclassified pedicle screw spinal systems as Class II devices only

D. Fraud-On-The-FDA Claims Would Result In Undesirable Practical Consequences

A holding that fraud-on-the-FDA claims are not preempted would also produce undesirable practical consequences. Absent an applicable privilege, *NLRB* v. *Sears, Roebuck & Co.*, 421 U.S. 132, 150-151 (1975), such claims would invite highly intrusive inquiries into FDA's internal deliberations. For example, respondents assert, as necessary elements of liability, that FDA did not know about the true intended use of the device in question; that FDA relied on petitioner's misrepresentation about that intended use; and that FDA would not have cleared the device for marketing in the absence of petitioner's alleged fraud. Pet. App. 8a-9a.

In litigating those issues, the parties would very likely seek discovery from FDA concerning agency officials' states of mind and the courses of action that agency decisionmakers might have taken under various hypothetical scenarios. It is the position of the United States that employees of the federal government are immune from third-party subpoenas issued in private litigation, that testimony must be sought under an agency's *Touhy* regulations, see generally *United States ex rel. Touhy* v. *Ragen*, 340 U.S. 462 (1951), and that an agency's denial of a request for testimony by agency employees is subject to review only in federal court and only under the "arbitrary" or "capricious" standard of the Administrative Procedure Act, 5 U.S.C. 706(2)(A). The lower federal courts, however, have taken divergent views on issues concerning third-party subpoenas issued by a federal court to federal employees. Compare, *e.g.*, *Comsat Corp.* v. *National Science Foundation*, 190 F.3d 269, 277-278 (4th Cir. 1999) (applying APA standard), with *Exxon Shipping Co.* v.

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for certain spinal uses, and it imposed four "special controls" for those uses. *Id.* at 40,027, 40,034-40,038. The record in this case does not address whether the devices that AcroMed marketed satisfied those limitations.

United States Dep't of Interior, 34 F.3d 774, 778-780 (9th Cir. 1994) (agency must produce evidence in response to a federal court subpoena, subject only to court's discretion to limit discovery under Fed. R. Civ. P. 26 and 45). Regardless of how that issue is ultimately resolved, widespread litigation could be expected on whether testimony and other evidence could be secured from FDA. This multidistrict litigation alone involves thousands of plaintiffs in more than 2000 cases that could be tried in several dozen different judicial districts. The prospect of such intrusive inquiries and attendant litigation would pose a significant potential for diverting FDA's resources from the important health mission that Congress has assigned to it and for distorting FDA's internal decisionmaking processes.

Nor would the undesirable consequences of fraud-on-the-FDA claims abate if the courts ultimately accept the government's position on when its officials can be required to testify. Parties would still be free to challenge any refusal to testify under the Administrative Procedure Act, and would retain every incentive to do so. And, in cases in which a government claim of privilege is sustained, a jury could only speculate about the crucial issues in the case. Such speculation would increase the danger that the jury's decision would conflict with FDA's judgment concerning whether it was defrauded and, if so, what should be done.

Permitting state-law suits for fraud on a federal agency could also distort the behavior of regulated entities. Those entities base their behavior largely on their understanding of how federal law has been applied in the past and how it will likely be applied in the future. If a regulated entity knows that juries applying the tort law of any one of the 50 States will play a central role in interpreting the entity's duties to the federal government, that concern could cause it to alter its behavior in unpredictable ways that may well be inconsistent with the efficient administration of the federal regulatory scheme. For example, if, in order to avoid a risk

that a jury in one of 50 States might conclude that they have withheld relevant information, regulated entities began to flood FDA with information that FDA does not need, it could significantly complicate the clearance process.

Fraud-on-the-FDA claims therefore pose a real danger of making it more difficult for FDA to perform its central mission of protecting the public health. That consequence can be avoided by a holding that such claims are impliedly preempted.

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted.

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IN THE

Supreme Court of the United States

THE BUCKMAN COMPANY,

Petitioner,

v.

PLAINTIFFS' LEGAL COMMITTEE,

Respondent.

ON WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

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Lewis v. Brunswick Corp., 107 F.3d 1494 (11th Cir. 1997), *cert. dismissed*, 523 U.S. 1113 (1998) 12

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21 C.F.R. § 807.100	21
21 C.F.R. § 807.100(b)(1)	21
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H.R. Conf. Rep. No. 105-399 (1997)	25
H.R. Rep. No. 94-853 (1976)	23
H.R. Rep. No. 98-857 (1984)	24
S. Rep. No. 73-493 (1934)	17
S. Rep. No. 105-43 (1997)	19
Kenneth P. Berkowitz, et al., *Congress Tries to Bridge the 'Label Gap' But Nobody Is Cheering*, Med. Mktg. & Media, Jan. 1998	26
William L. Christopher, *Off-Label Drug Prescription: Filling the Regulatory Vacuum*, 48 Food & Drug L.J. 247 (1993)	26
Deirdre Davidson, *Reform Eyed For Landmark Drug Law*, Legal Times, Sept. 11, 2000	10
Food and Drug Admin., Center for Devices and Radiological Health, Off. of Device Evaluation, *Annual Report: Fiscal Year 1998*	22-23
More Information for Better Patient Care: Hearings on S. 1477 Before the Senate Comm. on Labor and Human Resources, 104th Cong. 81 (1996)	25

Cited Authorities

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Robert L. Rabin, *Reassessing Regulatory Compliance*, 88 Geo. L.J. 2049 (2000) 10, 24, 25

Robert Samuelson, *Beware of a Regulatory Overdose*, Wash. Post, Sept. 5, 2000 10

INTEREST OF *AMICUS CURIAE*[1]

The Pharmaceutical Research and Manufacturers of America (PhRMA) is a voluntary, nonprofit association representing the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, healthier, and more productive lives.[2] These companies produce the majority of new medicines that are developed and marketed throughout the world. A number of PhRMA's members also are engaged in the development and sale of medical devices.

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1. This brief was authored by the *amicus* and counsel listed on its cover, and was not authored in whole or in part by counsel for a party. No one other than the *amicus* or its counsel made any monetary contributions to the preparation or submission of this brief. This brief is being filed in accordance with a consent agreement entered into by both parties, which has been filed with the Clerk.

2. PhRMA's brief is submitted on behalf of PhRMA members Abbott Laboratories, Allergan, Inc., ALZA Corporation, American Home Products Corporation (and subsidiaries), Amgen, Ares-Serono International, AstraZeneca LP, Aventis Pharma AG, Bayer Corporation Pharmaceutical Division, Biogen, Inc., Bio-Technology General Corp., Boehringer Ingelheim Corporation (and subsidiaries), Bristol-Myers Squibb Company (and subsidiaries), E.I. duPont de Nemours and Company, Elan Pharmaceuticals (and subsidiaries), Fujisawa Healthcare, Inc., Genentech, Inc., Genzyme Corporation, Gilead Sciences, Inc., Glaxo Wellcome Inc., Hoffman-La Roche Inc., Immunex Corporation, Johnson & Johnson (and subsidiaries), Knoll Pharmaceutical Company, Eli Lilly and Company, Merck & Co., Inc. (and subsidiaries), Novartis Pharmaceuticals Corporation, Nycomed Amersham Imaging, Organon Inc., Otsuka America Pharmaceutical, Inc., Pfizer Inc., Pharmacia Corporation, The Procter & Gamble Company, Purdue Pharma L.P., Sanofi-Synthelabo Inc., Schering-Plough Corporation, SCHWARZ PHARMA, Inc., SmithKline Beecham (and subsidiaries), Solvay Pharmaceuticals, Inc. and 3M Pharmaceuticals.

PhRMA's member companies will invest almost $26 billion this year in discovering and developing new medicines, leading the way in the search for cures. PhRMA estimates that the current average cost of developing a single new drug is approximately $500 million, and that the development process requires about fifteen years.[3] This lengthy development period already cuts significantly into the patent protection period that affords manufacturers their best opportunity to recover these enormous development costs. Opening the door to additional pre-approval burdens arising under state law, and casting doubt on the finality of federal device and drug approvals, would diminish the economic incentive for new device and drug development.

PhRMA's members are concerned that the lower court's decision, unless reversed, would improperly permit the states, through common-law fraud actions, to add a second, state-administered Food and Drug Administration (FDA) approval process. Allowing state courts and juries to second-guess FDA approval decisions would undermine the certainty and uniformity of the federal approval scheme, upon which manufacturers rely in developing and marketing their products. Moreover, the specific distortion of the federal regulatory regime upon which respondents' claims are based would, in practice, delay, or even eliminate, the availability of many new and competitive devices and drugs, to the detriment of PhRMA's members and the public health.

For these reasons, PhRMA joins petitioner The Buckman Company in urging this Court to reverse the lower court's holding on the question presented for review.

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3. This total includes time spent on (1) "pre-clinical" testing; (2) clinical testing of the drug on human populations; and (3) applying for and awaiting final FDA approval.

STATEMENT OF THE CASE

In the interest of judicial economy, PhRMA adopts the statement of the case as set forth in petitioner's brief.

SUMMARY OF ARGUMENT

The Medical Device Amendments of 1976, 21 U.S.C. § 360k(a) (MDA), to the Federal Food, Drug and Cosmetic Act of 1938, 21 U.S.C. §§ 301-397 (FFDCA), expressly and impliedly preempt respondents' claims. The lower court's holding to the contrary should be reversed.

The lower court erred in holding that the present case is controlled by *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996). In so doing, the lower court wrongly opened the door to disruptive second-guessing of FDA approval determinations by state courts, juries, and administrative agencies. At most, *Medtronic* holds that, where the federal regulatory regime governing medical devices has accorded broad discretion to manufacturers (such as in the design and manufacture of products), the MDA does not preempt the states from "filling in the gaps" in federal regulation by enforcing traditional common-law standards of behavior.

Here, however, respondents' state-law claims do not arise from traditional areas of state authority. Rather, they are premised on the peculiar theory that liability under state law arises from fraud on a *federal* agency. Nor do the state-law claims concern matters on which the federal regime has failed to speak or has given discretion to manufacturers. To the contrary, respondents' claims rest on a challenge to the validity of an *FDA approval determination* — a specific, adjudicative ruling by the FDA with respect to the device at issue. Thus, *Medtronic* does not control in this case.

Respondents' claims must be preempted. These claims challenge the legality of marketing an FDA-approved product. If state law could support such claims, plaintiffs

who believe that their injuries are associated with the use of any FDA-approved product could assert that the product was approved only because of "fraud," other alleged manufacturer misconduct, or because the FDA "got it wrong." Although federal law gives finality to FDA premarketing approvals, claims such as respondents' effectively add state approval requirements to this federal review. By imposing a state-law requirement different from, and in addition to, the federal requirement, recognition of respondents' claims would directly contravene § 360k(a).

State-based collateral review of FDA approval decisions also interferes with the legislative purposes of the FFDCA and MDA. The federal regulatory regime governing approval of devices and drugs accords uniformity and finality to the FDA approval process. In the premarket approval context, the FDA grants market access to a device or drug only after careful consideration of the product's possible benefits versus its potential risks for the labeled uses. Once the approval determination has been made, the product's manufacturer[4] enjoys the certainty that it may lawfully market its product in interstate commerce, so long as it does so in accordance with the approved labeling. This certainty is essential to facilitating the research, development, and marketing of new, innovative medical products, all of which carry possible risks, and none of which can be proven safe and effective in all circumstances.

Permitting state review of the FDA approval process would turn this system on its head. Even where, as here, the states purport to follow federal approval standards in assessing the validity of an FDA approval decision, the states may interpret those approval criteria inconsistently with

4. In this brief, "manufacturer" is intended to encompass manufacturers of medical devices and pharmaceuticals, as well as the regulatory agents of those manufacturers (such as petitioner).

Congressional intent or FDA practice. Manufacturers then would be faced with enormous and unfair potential liability for failing to comply with the *ex post facto* interpretation of the approval standards adopted by each state (or each state court or jury). As a result, a dual regime could radically delay, or even preclude, the introduction of beneficial new products.

This case aptly illustrates the adverse consequences of permitting state review of FDA approval decisions. Respondents' state-law claims are premised on the theory that the availability of petitioner's bone screws *itself* caused them harm, and that the FDA "got it wrong" in approving the screws as labeled due to petitioner's alleged fraud. If allowed to proceed, these claims would require state courts and juries to inquire into whether, in fact, the FDA "erred" in allowing the screws to be marketed.

In order for respondents to prevail, moreover, the reviewing state courts and juries would necessarily have to adopt an interpretation of federal standards *different* from that which has been adopted by Congress. Specifically, respondents assert that federal law requires an applicant for FDA approval to "truthfully" disclose to the FDA its subjective intent or expectation regarding the product's use. Since the early federal food and drug laws, however, Congress has made clear that the "intended use" statement in a premarket notification application is an objective description of the claims made in the labeling. Congress's objective construction of "intended use" reflects its long-standing effort to regulate the promotional claims made by manufacturers, rather than to interfere with the freedom of physicians to practice medicine in accordance with their professional judgment.

By necessitating, under state law, a broader construction of "intended use" than that intended by Congress, respondents' claims would inevitably expand the scope of

testing and review required for the approval of new drugs and devices. In addition, where off-label uses develop for such drugs and devices, as is commonly the case, respondents' broader construction of "intended use" would foreclose use of the "§ 510(k)" and Abbreviated New Drug Application processes established by Congress to accelerate new entry. Respondents' construction also would interfere with the delicate federal regulatory balance governing the dissemination of information regarding off-label uses.

The Supremacy Clause, U.S. Const., art. VI, cl. 2, and the Medical Device Amendments require preemption of state-law standards that permit the states to scrutinize the FDA approval process and second-guess the validity of FDA approval determinations. These standards, whether imposed through common-law causes of action or statutory schemes, would impermissibly disrupt the intended uniformity and certainty of the federal approval regime, and could lead to reduced availability of important medical products.

ARGUMENT

I. THE LOWER COURT WRONGLY OPENED THE DOOR TO SECOND-GUESSING OF FDA APPROVAL DETERMINATIONS BY STATE COURTS, JURIES, AND AGENCIES.

Respondents' state-law claims against petitioner are premised on the *very availability* of petitioner's bone screws. Without such availability, respondents claim, the surgical procedures that allegedly caused their injuries would never have been performed. Put another way, respondents assert that the FDA "got it wrong" in approving petitioner's bone screws, because the screws never would have been approved absent petitioner's alleged "fraud" during the approval process. Respondents thus seek to use their "fraud on the FDA" claims to set aside the FDA's determination that the screws at issue were entitled to a § 510(k) approval, *see* 21 U.S.C. § 360e(b)(1)(B), and could lawfully be marketed.

The court below, reversing its earlier position in *Michael v. Shiley*, 46 F.3d 1316 (3d Cir. 1995), permitted respondents' claims to go forward over preemption challenges. *In re Orthopedic Bone Screw Prods. Liab. Litig.*, 159 F.3d 817, 819, 823 (3d Cir. 1998). The majority believed that this Court's decision in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), required this result because (a) respondents were not challenging a specific federal requirement with respect to a device; and (b) respondents' challenge was premised on a federal standard of candor and thus supported, rather than contradicted, federal goals. 159 F.3d at 823. The lower court was wrong in both respects.

A. *Medtronic* Does Not Control This Case.

Medtronic is inapplicable in this case. At most, *Medtronic* stands for the proposition that, where the federal regulatory regime governing medical devices provides manufacturers with broad discretion in designing and manufacturing their products, the states are not precluded from "filling in the regulatory gaps" by imposing traditional common-law duties and statutory standards. 518 U.S. at 500-01 (plurality opinion); *id.* at 508 (Breyer, J., concurring in part and concurring in the judgment).[5] A majority of this Court in *Medtronic* concluded that the plaintiff's state-law negligence and product liability claims were not preempted by the MDA, 21 U.S.C. § 360k(a), because there were no specific federal regulations governing the manufacture or design of the device in question. 518 U.S. at 501 (plurality opinion); *id.* at 508 (opinion of Breyer, J.). The plurality opinion noted that the case at bar was

> quite unlike a case in which the Federal Government has weighed the competing interests

5. PhRMA recognizes that petitioner's brief asks this Court to reconsider its holding in *Medtronic*. Such reconsideration may in fact be appropriate in this case.

> relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers.

Id. at 501.

In this case, the federal government (*i.e.*, the FDA) has made a *specific* determination that petitioner's device is entitled to be sold as labeled. Thus, the FDA has "reached an unambiguous conclusion" in a "particular case," and "implemented that conclusion via a specific mandate on [petitioner]" — by granting § 510(k) approval. *See id.*

Indeed, FDA device approval determinations necessarily involve federal actions specific to a device, as they are decided on a case-by-case basis on the strength of a manufacturer's § 510(k) application or premarket test data. Further, the federal regulatory regime governing device approvals does not confer discretion on manufacturers with respect to initiating marketing, or leave "gaps" for states to fill with common-law causes of action: an FDA approval determination is the final word regarding whether a product may or may not be marketed in interstate commerce as labeled.

Moreover, respondents' claims are of a different character from those in *Medtronic*. *Medtronic* involved state-law claims in areas of traditional state concern; *i.e.*, product liability and negligence. 518 U.S. at 481. Here, by contrast, respondents' claims are based on the odd premise that liability under *state* law may arise when an actor commits "fraud" on a *federal* agency. Certainly, the relationship between federal agencies and those they regulate is not a field of historic state concern or legislation. *See* Brief of United States, at 15. Thus, the "assumption that the historic

police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress" does not apply here. *Medtronic*, 518 U.S. at 485 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

Because this case involves an attempt to overturn a specific federal approval determination, using a non-traditional theory of state-law liability based solely on alleged violations of federal duties, *Medtronic* cannot control its outcome.

B. State-Law Causes Of Action Or Standards Permitting Collateral Review Of FDA Approval Decisions Must Be Preempted.

In sustaining respondents' claims, the court below wrongly opened the door to second-guessing of federal approval determinations by state courts, juries, and administrative agencies.

These claims, resting on the alleged invalidity of FDA approval decisions, add a layer of state-based review to the FDA approval process. They permit the states to examine and determine whether the FDA was caused to err in granting market access. This would, in turn, allow states, through the imposition of massive civil liability, to effectively override the FDA's approval decision.

This type of claim inherently runs afoul of the Constitution's Supremacy Clause. U.S. Const., art. VI, cl. 2; *see also Hines v. Davidowitz*, 312 U.S. 52, 67 (1941) (the Supremacy Clause requires preemption where state law conflicts with federal law or "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress"). The federal regime confers primary enforcement jurisdiction on the FDA, the purpose of which is to accord finality to the agency's approval determinations. *See* 21 U.S.C. §§ 371(a), (h), 393 (charging the FDA with

enforcement jurisdiction over the FFDCA and MDA, and particularly with ensuring that drugs and medical devices are safe and effective). This finality provides manufacturers with certainty that they may lawfully place their products in interstate commerce. Finality is critical to the approval process, which, as it stands, involves tremendous cost and risk to applicants.

Applicants for FDA approval frequently spend many years and millions of dollars researching, developing, and testing new products before the FDA approval process even begins. Obtaining approval often means spending millions more in testing or running clinical trials. *See* Robert Samuelson, *Beware of a Regulatory Overdose*, Wash. Post, Sept. 5, 2000, at A25 (citing studies reporting that, on average, developing a new drug costs from $200 to $500 million and takes about 15 years). Further, the time spent in seeking FDA approval cuts into the statutory patent protection period afforded to new, innovative products. *See* 35 U.S.C. § 154; *see also* Deirdre Davidson, *Reform Eyed For Landmark Drug Law*, Legal Times, Sept. 11, 2000, at 1 (citing study reporting that pharmaceuticals enjoy an average of 11.5 years of patent protection, while other types of products are protected for an average of 18 years). The longer the process takes, the less time a manufacturer has to market its product on an exclusive basis and recoup its development costs.

In reviewing a premarket approval application for a medical device or drug, the FDA carefully balances the potential benefits and possible risks of the product in question for its labeled uses. *See* 21 U.S.C. §§ 355(d), 360e(d); *see also* Robert L. Rabin, *Reassessing Regulatory Compliance*, 88 Geo. L.J. 2049, 2075 (2000). Both the FDA and the applicant know that no product for which approval is sought can be proven entirely safe or effective; the FDA's role is to decide whether the product's potential health

benefits for the proposed uses outweigh its possible dangers. If the FDA so determines, it will approve the product to be marketed for the uses specified in proposed labeling. 21 U.S.C. §§ 355(d); 360e(d).

Allowing state courts and juries to "look behind the labeling" and second-guess FDA approval determinations would turn this system on its head. The *very existence* of state-based re-evaluations of the FDA approval process subverts the finality of the FDA's decisions. Any time the use of an FDA-approved product allegedly causes harm, plaintiffs could assert, as here, that the federal approval decision was erroneous, whether due to "fraud," FDA mistake, or for other reasons. The FDA approval determination would then be subject to intrusive scrutiny by state courts and juries. Even assuming that the states purported to follow *federal* standards in examining the approval process, the states might interpret such standards differently from Congress and the FDA. Permitting such an inquiry would raise the significant possibility that FDA approval determinations would be judged "invalid" by state decision-makers. The question of whether any given federal approval decision was valid also could be answered differently from court to court and from jury to jury, leaving the approval status of a medical device or drug entirely up in the air.

Additionally, allowing common-law challenges to FDA approvals could open the door to state administrative schemes designed to provide collateral review of FDA approvals. If common-law, *de facto* challenges to FDA approval decisions are permissible, it might be difficult to prevent a state from establishing an administrative scheme to review FDA approvals before permitting in-state marketing. As a result, manufacturers could find themselves forced to apply for approval in *each state* before being able to market a product in interstate commerce.

Permitting state collateral review of federal approval decisions would impermissibly disrupt the federal approval system. Manufacturers could no longer rely on FDA approval determinations in marketing their products. Rather, because they could face *ex post facto* state-based challenges to FDA approval decisions (leading to potentially enormous liability under state law), manufacturers would be left with massive uncertainty regarding the legality of marketing any given product. This uncertainty could have severe and adverse effects on the research and development of medical devices and drugs: because the risks associated with new products would be exponentially higher, many potentially beneficial devices and drugs might never be developed.

The Supremacy Clause, U.S. Const., art. VI, cl. 2, does not permit state law to undermine the finality of FDA approval determinations in this manner. The Supremacy Clause mandates preemption of state common-law or legislative standards that permit scrutiny of the federal regulatory process and challenges to the approval determinations that result therefrom. *See Leslie Miller, Inc. v. Arkansas*, 352 U.S. 187, 190 (1956) (per curiam) (invalidating the application of a state licensing requirement to federal contractors whose bids had been approved under federal criteria; such a requirement gives the state "a virtual power of review over the federal determination," and "does not merely touch the Government servants remotely by a general rule of conduct; it lays hold of them in their specific attempt to obey orders and requires qualifications in addition to those that the Government has pronounced sufficient") (quoting *Johnson v. Maryland*, 254 U.S. 51, 57 (1920)).[6]

6. Several lower courts have recognized this principle. *See, e.g., Lewis v. Brunswick Corp.*, 107 F.3d 1494, 1505 (11th Cir. 1997), *cert. dismissed*, 523 U.S. 1113 (1998); *Mitchell v. Collagen Corp.*, 67 F.3d 1268, 1283 (7th Cir. 1995) (the MDA preempted plaintiffs' "fraud on the FDA" claims because such claims "require[] (Cont'd)

In addition, the express preemption provision of the MDA, 21 U.S.C. § 360k(a), requires preemption of this category of claims in the context of medical devices. A state-law claim that requires the collateral review of the FDA's approval decision with respect to a device necessarily imposes a requirement (*i.e.*, another stage of review) that is "different from, or in addition to," the requirements for federal approval. In other words, once a device has, in the FDA's view, met the federal criteria for approval, section 360k(a) precludes a state from adding the effective requirement that the device satisfy *state*-administered premarket criteria.

Preempting state actions that permit re-evaluation of FDA approval decisions would not mean that "fraud on the FDA" or other unlawful conduct occurring during the approval process would go uncorrected or unpunished.

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a court, applying state law, to perform the same functions initially entrusted to the FDA") (quoting *Michael v. Shiley, Inc.*, 46 F.3d 1316, 1329 (3d Cir. 1995)), *judgment vacated*, 518 U.S. 1030 (1996), *on remand*, 126 F.3d 902 (7th Cir. 1997); *Talbott v. Bard, Inc.*, 63 F.3d 25, 29 (1st Cir. 1995) (noting the disruptive effect that state "fraud on the FDA" claims would have on the uniformity of FDA decisions, and observing that the FDA has "broad" authority to withdraw approval decisions and initiate criminal prosecutions against manufacturers who commit fraud); *Reeves v. Acromed*, 44 F.3d 300, 307 (5th Cir. 1995) ("Allowing a jury or court to second-guess the FDA's enforcement of its own regulations contravenes Congress' expressly stated intent in § 360k(a) to eliminate attempts by states to impose conflicting requirements on medical device manufacturers"); *Kuiper v. American Cyanamid Co.*, 131 F.3d 656, 666 (7th Cir. 1997) (finding state "misbranding" claims against herbicide manufacturer preempted where manufacturer's label conformed with EPA-approved label; "FIFRA does not allow states to second-guess EPA's labeling decisions under the guise of enforcing the requirements of FIFRA itself"), *cert. denied*, 523 U.S. 1137 (1998).

The FDA has primary responsibility for policing violations of its regulations. It also has ample authority to withdraw approval and/or seek criminal penalties where it finds that violations have been committed. *See Heckler v. Chaney*, 470 U.S. 821, 835 (1985).[7] Given its central role in reviewing and approving devices and drugs, the FDA is in the best position to decide whether a "fraud" or other wrong has occurred, and, if so, how the culpable party should be penalized.[8]

The integrity of the FDA approval regime requires preemption of state-law standards — including respondents' "fraud on the FDA" claims — that permit *ad hoc* (or systematic) challenges to the validity of FDA approval decisions. Allowing such standards to exist would undermine the finality and uniformity of federal approval decisions, and, as a result, distort manufacturer behavior in a manner that undercuts the purposes of the statutory scheme. The consequence of permitting state courts, juries, and agencies to second-guess FDA approval decisions could be to slow the approval process and expose manufacturers to potentially massive liability simply for marketing FDA-approved products. This result is not permitted under the Supremacy Clause or section 360k(a) of the MDA.

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7. Manufacturers frequently are "repeat players" before the FDA, and want to maintain credibility before the agency to ensure the continued approvals of their products. As a result, they have a strong incentive not to defraud the agency or engage in other wrongful conduct during the approval process.

8. Congress's decision not to create a federal private right of action to enforce the FFDCA and MDA does not suggest that injured parties should be permitted to seek compensation under *state* law. To the extent that there are policy reasons for permitting injured parties to recover when FDA approval is wrongfully secured, preservation of the finality and uniformity of the federal regime mandates that such a remedy be granted by Congress, not haphazardly by the states.

II. RESPONDENTS' "INTENDED USE" POSITION CONFLICTS WITH THE USE OF THAT TERM IN THE FFDCA AND STATE-LAW CLAIMS BASED ON THAT POSITION ARE NECESSARILY PREEMPTED BY THE MEDICAL DEVICE AMENDMENTS OF 1976.

This case brings into sharp focus the problems with permitting state review of the federal approval process even where a federal standard is purportedly applied. At a minimum, respondents' claims would require state courts and juries to "look behind" the FDA decision-making process to determine what information was conveyed to the FDA; whether the FDA relied upon alleged misstatements; and whether, but for the alleged fraud, petitioner's bone screws would have been FDA-approved. As the Solicitor General has advised this Court, this examination itself would unduly impair the FDA review process. United States Br., at 16-18.

Respondents' claims also are preempted because their "intended use" theory would severely disrupt the federal regime. If respondents' subjective intent construction were to be adopted in even one jurisdiction, manufacturers would be forced to change their behavior during the approval stage in a manner that would severely undermine the "substantial equivalency" approval process and hinder the development of both breakthrough and follow-on devices and drugs.

A. Respondents' Claims Are Expressly Preempted Because They Would Impose A State-Law Requirement For "Intended Use" Disclosure That Is Different From, And In Addition To, The Requirement Under Federal Law.

As noted, respondents here assert that the FDA, as a result of petitioner's "fraud," "got it wrong" in approving petitioner's bone screws. In particular, respondents allege that petitioner misled the FDA regarding the screws' intended use, and that the FDA relied upon this misrepresentation in clearing the screws for market access. *Orthopedic Bone Screw Prods. Liab. Litig.*, 159 F.3d at 820. Because the screws were FDA-approved and available to physicians, physicians were able to use the screws off-label to perform pedicle surgeries, causing respondents' alleged physical injuries. *Ibid.*

Respondents' claims of fraud are based on the premise that federal law requires an FDA applicant to "truthfully" disclose any bona fide, subjectively intended or expected use for the device in question. Under federal law as defined by Congress, however, an FDA applicant's statement of "intended use" in its § 510(k) application is solely an *objective* description of the scope of marketing authority requested in the proposed labeling.

Federal law does not require a manufacturer to reveal its subjectively intended or expected uses for a device or drug in seeking FDA approval. Rather, the statement of "intended use," as defined by Congress, is a term of art objectively describing a manufacturer's requested authority for FDA-approved labeling and promotional claims. Congress's objective interpretation of intended use reflects its attempt to accommodate both the FDA's premarket review authority and the freedom of physicians to practice in accordance with their professional judgment.

Throughout the administration of the federal food and drug laws, "intended use" has been understood to refer only to the use set forth for a product in the product's labeling. The Food, Drug and Cosmetic Act of 1938 (FFDCA), Pub. L. No. 75-717, 52 Stat. 1040 (1938), established the requirement that, before the marketing of a new drug, a manufacturer must affirmatively demonstrate that the drug is safe "for use under the conditions prescribed, recommended, or suggested *in the proposed labeling thereof*." *Id.* § 505(d)(1), 52 Stat. at 1052 (codified as amended at 21 U.S.C. § 355(d)(1)) (emphasis added). This explicit limitation of premarket review to review of the uses claimed in the labeling illustrates Congress's clear intention to limit "intended uses" to uses labeled or promoted by the manufacturer, as opposed to all uses that the medical community may find attractive.

The FFDCA's legislative history recognized the essential tie between manufacturer claims and FDA authority to conduct premarket review:

> The use to which a product is to be put will determine the category into which it will fall. . . . *The manufacturer of the article, through its representations in connection with its sale, can determine the use to which the article is to be put.*

S. Rep. No. 73-493, at 2-3 (1934) (emphasis added).[9]

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9. Congress's subsequent amendments to the food and drug laws consistently adhered to the objective interpretation of "intended use." *See, e.g.*, Pub. L. No. 87-781, § 102(c), 76 Stat. 780, 781-82 (1962) (requiring manufacturers to make a premarket showing of effectiveness, as well as safety, for each "use . . . prescribed, recommended, or suggested in the labeling") (codified at 21 U.S.C. § 355(d)(1)); Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (creating an "Abbreviated New Drug Application" (ANDA) procedure under which generic versions of (Cont'd)

As with drugs, in regulating medical devices, Congress consistently has limited the definition of "intended use" to uses claimed in labeling or promotional materials. *See* 21 U.S.C. § 360c(a)(1)(C)(3)(A) (a Class III device's "effectiveness" is based on whether it is demonstrated that "the device will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling of the device").

In fact, recently, Congress has explicitly declared that the statement of "intended use" in a premarket notification provision for a medical device is purely objective, and does not incorporate an applicant's subjective intent or expectations. In 1997, after the initiation of the present lawsuits against petitioner, Congress amended the FFDCA to include an instruction to the FDA that "[a]ny determination by [the FDA] of the intended use of a device [submitted for § 510(k) approval] shall be based upon the proposed labeling[.]" Food and Drug Administration Modernization Act, Pub. L. No. 105-115, 111 Stat. 2296 (1997) (FDAMA) (codified at 21 U.S.C. § 360c(i)(1)(E)(i)). Thus, under FDAMA, the FDA may not consider a § 510(k) applicant's subjectively intended uses for a device.

The legislative history of FDAMA makes Congress's intent unmistakable. The Senate Report provided:

> With the "Medical Device Amendments of 1976," Congress intended that device classification and approval decisions be made based on the intended use of devices as described in labeling. . . .

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pioneer drugs could receive expedited approval; limiting the FDA's authority to approve ANDAs to those where "the labeling proposed for the new drug is the same as the labeling proposed for the [pioneer] drug") (codified at 21 U.S.C. § 355(j)(2)(A)(v)).

> For premarket notification submissions, the labeling proposed in the submission will be controlling of a device's intended use. If the intended use is the same or sufficiently similar to the intended use of a predicate device, then the device may be found to be substantially equivalent to the predicate. *No considerations outside of the proposed labeling for the § 510(k) device should bear on the question of whether or not the proposed labeling of the newer device is compatible with the labeling of the predicate device.*

S. Rep. No. 105-43, at 27 (1997) (emphasis added).[10]

In sum, Congress has repeatedly and expressly restricted the definition of "intended use" to claims made in proposed

10. Although it refused to alter the objective understanding of "intended use," Congress enacted a provision directed at remedying the problem of potentially harmful uses that were *not* "intended uses." Specifically, Congress temporarily authorized the FDA, in reviewing a premarket notification submission, to require a manufacturer to include in the proposed labeling of its device a statement of "appropriate information" about an unclaimed use, where such a use is foreseeable and could pose a potential for harm. FDAMA, § 205, 111 Stat. at 2337 (codified at 21 U.S.C. § 360c(i)(1)(E)(i)); *see also* 21 U.S.C. § 360c(i)(1)(E)(iv) (five-year sunset on FDA authority).

An unclaimed use for which the FDA may require "appropriate information," however, still is not an "intended use" as that term of art has been defined by Congress. Rather, in enacting this provision, Congress explicitly segregated the "intended use" determination — which establishes the "substantial equivalency" necessary for § 510(k) approval — from the consideration of what, if any, further information should appear on the label regarding potentially dangerous off-label uses.

labeling.[11] To sustain respondents' theory of the case, however, state courts would have to reject this established construction and adopt a subjective interpretation of "intended use," thereby imposing disclosure obligations different from, and in addition to, those imposed under federal law. Any state action of this kind would clearly run afoul of section 360k(a) of the MDA.

B. Sustaining Respondents' Claims Would Severely Limit "Substantial Equivalency" Approvals For Medical Devices And Hinder Research And Development Of New Devices And Drugs.

By creating uncertainty regarding the meaning of "intended use," respondents' claims ultimately would hamper the research and development of new and follow-on medical devices and drugs.

Sustaining respondents' claims could severely hinder the ability of medical device manufacturers to seek expedited § 510(k) approval based on a device's "substantial equivalency" to a preexisting device. *See* 21 U.S.C. § 360e(b)(1)(B). Under § 510(k), a manufacturer seeking to market a new device may avoid the extended premarket

11. Four members of this Court, dissenting in *Food & Drug Administration, et al. v. Brown & Williamson Tobacco Corp., et al.*, __U.S.__, 120 S. Ct. 1291, 146 L. Ed. 2d 121 (2000), took the position that "intended use" can, for purposes of determining the FDA's jurisdiction over drugs, incorporate uses that are fostered or expected by manufacturers. 120 S. Ct. at 1320-22, 146 L. Ed. 2d at 157-59 (Breyer, J., dissenting). The dissent's discussion, however, concerned the FDA's alleged authority to regulate products whose objectively "intended uses" are discernible from the circumstances surrounding the products' *marketing*. 120 S. Ct. at 1320, 146 L. Ed. 2d at 157. *Brown & Williamson* did not involve the disclosure requirements for FDA approval. None of the regulations cited by the dissent in that case suggests that the "intended use" statement in an application for § 510(k) approval incorporates a manufacturer's future expectations or desires regarding the product's use.

approval process by demonstrating that the device is "substantially equivalent" to a predicate device. *Id.*; *see also Medtronic*, 518 U.S. at 477-79. The manufacturer must submit a premarket notification to the FDA describing, among other things, the "intended uses" of the device. 21 C.F.R. § 807.92(a)(5). If the FDA determines that the proposed device is "substantially equivalent" to its predicate for the specified "intended uses," it will grant approval. *Id.* § 807.100.

Importantly, a manufacturer may not secure § 510(k) approval for a device with materially different or additional "intended uses" from those of its predecessor. 21 U.S.C. § 360c(i)(1)(A) ("substantial equivalence" of devices requires that the devices have the same intended uses); 21 C.F.R. § 807.100(b)(1). Thus, where a new device has uses in addition to those of its predicate, the manufacturer is precluded from seeking expedited approval.

In the § 510(k) context, situations frequently arise where uses have developed for a predicate device beyond those approved by the FDA. Once a predicate device has been placed on the market, medical practitioners are free to adopt such off-label uses. By the time "substantial equivalency" approval is sought, these off-label uses are often documented in scientific literature, making them clearly foreseeable to § 510(k) applicants.

If respondents' claims are not preempted, a § 510(k) applicant could face potentially massive state fraud liability if it failed to list as "intended uses" all foreseeable uses of the device it wished to market. Plaintiffs claiming to be harmed in connection with a foreseeable off-label use could (and likely would) allege, as here, that the manufacturer subjectively intended the device to be put to that use — either in lieu of, or in addition to, the listed "intended

use" — and defrauded the FDA by failing to disclose such intent.[12]

If, to protect themselves from claims such as respondents', manufacturers disclosed all potential uses as "intended," they would be ousted from the § 510(k) process and forced to submit their devices instead to the premarket approval process.[13] This would radically change the current trend in device approval applications, *see* Food and Drug

12. The fact that respondents in this case assert that petitioner committed "fraud on the FDA" by providing an allegedly *pretextual* "intended use" statement would not alter this result. As a practical matter, a manufacturer could face "fraud on the FDA" claims any time an off-label use allegedly caused harm, regardless of whether such claims were based on an allegedly pretextual "intended use" statement or on an alleged failure to disclose an additional subjectively intended use. The manufacturer also would face potentially enormous litigation costs associated with either type of "fraud on the FDA" claim. Here, for example, the issue of whether petitioner falsely asserted a pretextual "intended use" for its bone screws is inherently factual in nature. Its resolution would require a determination of, among other things, (1) whether petitioner had a bona fide intent to market the screws in accordance with their listed "intended use"; (2) whether petitioner in fact intended for the screws to be marketed for pedicle surgeries; (3) precisely what was disclosed or not disclosed to the FDA; and (4) whether the FDA was misled by petitioner's alleged misrepresentation.

13. A manufacturer could not defend itself from claims such as these merely by disclosing to the FDA all foreseeable uses, without seeking either approval or "contraindication" labeling therefor. This is because, with respect to any off-label use for which labeling is *not* sought, plaintiffs could assert, as here, that the manufacturer subjectively intended the use to be adopted, yet failed to reveal such intent to the FDA. As a result, a manufacturer's only affirmative defenses to such a claim would be either: (1) that it *did* subjectively intend for the off-label use in question to be adopted, *and* disclosed such intent to the FDA by seeking approval for that use; or (2) that it *did not* intend the use, and foreclosed it by seeking contraindication labeling.

Admin., Center for Devices and Radiological Health, Off. of Device Evaluation, *Annual Report: Fiscal Year 1998* 21 (reporting that, during fiscal year 1998, 4,623 original § 510(k) applications were filed, as compared with 55 original premarket approval applications); *Medtronic*, 518 U.S. at 479-80 (reporting that, in 1990, 80% of new Class III devices were approved through the § 510(k) mechanism), and would thwart the salutary legislative purposes for which the expedited approval scheme was enacted. 518 U.S. at 478 (noting that the scheme was intended to "prevent manufacturers of grandfathered devices from monopolizing the market while new devices clear the PMA hurdle, and to ensure that improvements to existing devices can be rapidly introduced into the market").

In addition to directly undermining the § 510(k) process, sustaining respondents' claims would impede the approval of new medical devices. Because the threat of state fraud liability would force manufacturers to disclose and rigorously test for all potential uses and seek labeling therefor, these claims would work to significantly slow the already laborious premarketing approval process. This adverse consequence conflicts with the MDA's goal of ensuring the ready availability of safe and effective medical devices. *See* H.R. Rep. No. 94-853, at 12 (1976).

The adverse effects of allowing respondents' claims also could spill over into the drug approval context. Applicants for FDA approval of a drug must list the drug's intended indications. *See* 21 C.F.R. § 314.50(c)(2). Claims such as respondents' therefore could be asserted any time a foreseeable off-label use caused harm. To avoid exposure to such claims, drug approval applicants presumably would be forced to shoulder the same pre-approval burden as medical device applicants — namely, testing and seeking labeling for all known or foreseeable uses of proposed drugs. Thus,

as with medical devices, the existence of respondents' claims likely would raise costs for and slow all drug approvals. Generic drug applications, which require manufacturers to use labeling identical to the pioneer predecessor's, would be particularly affected, as off-label uses of pioneer drugs are widespread. *See* Rabin, 88 Geo. L.J. at 2078 (off-label uses of drugs are "critical to adequate health care" and are widespread in the pediatric and cancer fields). The required disclosure of such uses would foreclose access to the Abbreviated New Drug Application process under the FFDCA. *See* 21 U.S.C. § 355(j). The end result — diminished availability of both pioneer and generic medicines — would be directly at odds with Congressional intent. *See, e.g.*, H.R. Rep. No. 98-857, pt. 1, at 14 (1984) (Abbreviated New Drug Application process was intended "to make available more low cost generic drugs by establishing a generic drug approval procedure for pioneer drugs first approved after 1962").

C. Sustaining Respondents' Claims Would Impede The Dissemination Of Information Regarding Off-Label Uses Of Devices And Drugs.

Respondents' intent theory also would disrupt the delicate federal regulatory balance that has been struck with respect to the proper role of manufacturers in the dissemination of information regarding off-label uses.

Congress recognizes the importance of limiting federal regulatory interference with the practice of medicine by health care professionals, and specifically with physicians' freedom to use medical devices and drugs off-label. With respect to medical devices, Congress has declared:

> Nothing in [the FFDCA] shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship.

21 U.S.C. § 396. As its legislative history explains, this section was intended to restrict regulatory interference with off-label uses of devices. *See* H.R. Conf. Rep. No. 105-399, at 219 (1997) ("The conference agreement includes a provision intended by the conferees to emphasize that the FDA should not interfere in the practice of medicine. Specifically, the conferees note that the off-label use of a medical device by a physician using his or her best medical judgment in determining how and when to use the medical product for the care of a particular patient is not the province of the FDA").

Off-label uses have long been viewed by Congress and the FDA as a rational and beneficial part of the practice of medicine. *See, e.g.*, 59 Fed. Reg. 59820, 59821 (1994) (the FDA has long held that "'unlabeled' uses may be appropriate and rational in certain circumstances, and may, in fact[,] reflect approaches to drug therapy that have been extensively reported in medical literature"); *More Information for Better Patient Care: Hearings on S. 1477 Before the Senate Comm. on Labor and Human Resources*, 104th Cong. 81 (1996) (Statement of William B. Schultz, FDA Deputy Comm'r for Policy) ("[O]ff label uses of approved products are appropriate, rational, and accepted in medical practice. FDA knows that there are important off label uses of approved drugs"). Such uses are prevalent, and even predominant, in important fields such as oncology and pediatrics. *See* Rabin, 88 Geo. L.J. at 2078; *see also Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51, 56 (D.D.C. 1998), *order amended*, 36 F. Supp. 2d 16 (D.D.C. 1999), *appeal dismissed, judgment vacated in part on other grounds by Washington Legal Found. v. Henney*, 202 F.3d 331 (D.C. Cir. 2000). In the case of AIDS, experts report that between ninety and one hundred percent of pharmaceutical treatments, including the antiretroviral

"cocktail" therapies, are off-label. *See* Kenneth P. Berkowitz, et al., *Congress Tries to Bridge the 'Label Gap' But Nobody Is Cheering*, Med. Mktg. & Media, Jan. 1998, at 39-40. Off-label uses frequently constitute the standard of good medical care. *See Washington Legal Found.*, 13 F. Supp. 2d at 56.

Congress had a compelling practical reason for structuring the FFDCA to allow off-label uses — medicine simply moves faster than the FDA possibly can:

> New uses for drugs are often discovered after FDA approves the package inserts that explain a drug's approved uses. Congress would have created havoc in the practice of medicine had it required physicians to follow the expensive and time-consuming procedure of obtaining FDA approval before putting drugs to new uses.

United States v. Algon Chem., Inc., 879 F.2d 1154, 1163 (3d Cir. 1989) (quoting *Chaney v. Heckler*, 718 F.2d 1174, 1180 (D.C. Cir. 1983), *rev'd on other grounds*, *Heckler v. Chaney*, 470 U.S. 821 (1985)). *See* William L. Christopher, *Off-Label Drug Prescription: Filling the Regulatory Vacuum*, 48 Food & Drug L.J. 247, 261 (1993) (the FDA "could not review drugs . . . at a pace equal to that at which physicians discover off-label uses").

The FDA has recognized the need for disseminating adequate information regarding off-label uses and has attempted to regulate the manner and extent to which manufacturers can participate in the development and dissemination of such information. *See Washington Legal Found.*, 13 F. Supp. 2d at 56-58. As Judge Cowen stated in his dissent below, given the FDA's acceptance of off-label uses, "difficult and subtle balancing is called for in evaluating manufacturers' roles in the creation and distribution of information about [such] uses[.]" 159 F.3d at 831;

see also 59 Fed. Reg. 59820, 59823 (1994) (the FDA has recognized "the delicate balance required to accommodate the need for industry-supported scientific and educational activities and the statutory mandate that products be safe and effective for their intended uses").

Sustaining respondents' claims would wreak havoc on this balancing by permitting state courts and juries to force manufacturers, to the extent they are able, to eliminate off-label uses entirely. As discussed above, to avoid massive state "fraud" liability, manufacturers would be forced to include as many uses as possible "on-label." Further, the threat of state liability would discourage manufacturers from providing information regarding and contributing to efforts to study alternative uses of their products, since such efforts might be viewed as evidence of manufacturers' subjective intent to market their products for such uses. Thus, sustaining respondents' claims could curtail the information flow relating to off-label uses in a sweeping and misdirected manner that is discordant with the federal regulatory scheme, and further compels reversal of the decision below.

CONCLUSION

Claims such as respondents' — which are premised on the alleged invalidity of an FDA approval determination — are preempted by federal law. Allowing such claims would improperly impose an additional layer of state review of FDA approval decisions, undermining the finality and certainty of the federal approval scheme. Sustaining respondents' claims also would introduce a new theory of "intended use," which would distort manufacturer behavior and reduce the availability of beneficial medical devices and drugs to the public.

For all of the foregoing reasons, this Court should reverse the lower court's decision.

Respectfully submitted,

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IN THE

Supreme Court of the United States

THE BUCKMAN COMPANY,
Petitioner,

v.

PLAINTIFFS' LEGAL COMMITTEE,
Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Third Circuit

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BRIEF OF PRODUCT LIABILITY ADVISORY COUNCIL, INC., AS *AMICUS CURIAE* IN SUPPORT OF THE PETITIONER

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QUESTION PRESENTED

Whether a state-court plaintiff can pursue a state-law tort claim alleging that a medical device was approved and marketed as a result of fraud on the Food and Drug Administration, or whether such a claim is impliedly preempted by the federal law governing the marketing clearance process for medical devices.

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INTEREST OF THE AMICUS CURIAE

Product Liability Advisory Council, Inc. ("PLAC") is an association of industrial companies formed for the principal purpose of submitting *amicus curiae* briefs in appellate cases involving significant issues affecting the law of product liability. Its members include manufacturers of a wide variety of products, including pharmaceuticals, medical devices, pesticides, aircraft, foodstuffs, and chemicals, who are governed by comprehensive federal safety regulations and statutes, including statutes with preemption provisions. PLAC and its members therefore have a strong interest in the proper resolution of conflicts between the requirements of federal statutes and regulations, on the one hand, and state tort law, on the other.[1]

STATEMENT

Respondent represents thousands of plaintiffs who have sued Petitioner and others for damages and equitable relief for injuries allegedly incurred as a result of surgical implantation of certain screws for spinal fixation. Some of the asserted claims charge Petitioner The Buckman Company ("Buckman") and medical device manufacturers with having defrauded the Food and Drug Administration ("FDA"). The decision below denominates these as "'fraud on the FDA' claim[s]." Pet. App. 1a.

The "fraud on the FDA" claims against Buckman do not allege that the screws were defective under product liability, negligence, or warranty principles. Nor do they allege that the devices were mislabeled in a manner on which plaintiffs or their physicians relied to plaintiffs' detriment. Rather, they allege

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[1] Letters from the parties consenting to the filing of this brief have been lodged with the Clerk of the Court. Pursuant to Rule 37.6, PLAC states that no counsel for a party has authored this brief in whole or in part and that no person or entity other than PLAC or its members has made a monetary contribution to the preparation or submission of this brief.

that (a) in applying in 1985 for FDA marketing clearance for the devices, Buckman "intentionally and falsely represented to the FDA" that the devices were "intended for use in appropriate fractures of long bones of both the upper and lower extremity and such other flat bones"; (b) in fact, "the . . . device was intended exclusively for use in the spine"; (c) the FDA "was ignorant of the fact that these devices and device components were intended by [the defendants] to be used as pedicle screw fixation devices"; (d) the FDA would not have approved the device for marketing had it known the manufacturer's actual subjective intent; and (e) as a result of that conduct, the plaintiffs represented by Respondent suffered physical harm. Pet. App. 8a-9a.

The application in question was made pursuant to what is commonly called a "section 510(k) notification," which is provided for in the Medical Device Amendments of 1976 ("MDA") and codified at 21 U.S.C. §§ 360c(f)(1)(A)(i)-(ii) & 360e(b)(1)(B). Under that process the FDA can permit the marketing of medical devices, such as the devices in question, that are "substantially equivalent" to any device marketed before the MDA's effective date and "grandfathered in" by the MDA under 21 U.S.C. §§ 360c(f)(1)(A)(i) & 360e(b)(1)(A).

FDA regulations in effect at the time of the alleged fraud specified the information that a device manufacturer had to provide to the FDA in a section 510(k) notification. *See* 21 C.F.R. § 807.87 (1985). Those regulations did not state that the manufacturer had to notify the FDA of the manufacturer's subjective intent regarding possible post-clearance "off-label" uses to which it hoped physicians might put the device. Instead, the regulations required the manufacturer to submit written materials that the manufacturer proposed to use overtly to describe for the medical community the uses for which the device would be intended if approved by the agency – specifically, "[p]roposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use." 21 C.F.R. § 807.87(e) (1985).

Nevertheless, the court of appeals held that neither the MDA's express preemption provision, 21 U.S.C. § 360k, nor implied preemption principles preempted "fraud on the agency" claims alleging that, in connection with the section 510(k) notification, Buckman had deceived the FDA by not telling the agency that the manufacturer subjectively "intended [the devices] to be used" for spinal fixation, rather than "in appropriate fractures of long bones of both the upper and lower extremity and such other flat bones." Pet. App. 8a-9a. The court of appeals thus held that a state may create and enforce a state common-law standard that makes medical device manufacturers liable for omitting from their section 510(k) notifications information not required by FDA regulations. The court further held that causation could be based upon a jury's finding, without any prior ruling or opinion by the FDA, that the agency would have withheld clearance to market the device had that information been provided.

SUMMARY OF ARGUMENT

Federal law impliedly preempts Respondent's state-law "fraud on the FDA" claims because those claims would impede the accomplishment and execution of the full purposes and objectives of Congress with respect to the MDA and its implementing regulations. The decision below permits private rights of action that are based solely on alleged violations of federal laws requiring information disclosures to a federal agency, rather than on any allegation that a product caused harm because it was unreasonably unsafe, defective, or mislabeled. It thereby permits individual states to maintain and enforce state laws that require manufacturers to provide to the FDA not only the information the FDA itself requires in determining whether to permit a device to be marketed, but additional information that state courts and juries may decide should have been provided to the FDA under their various interpretations of the MDA and FDA

regulations, even if those interpretations conflict with the FDA's own decisions.

If left intact, the decision below will foster interference with the FDA's fundamental functions of (i) determining what information should be required by the agency in deciding whether to allow new medical devices to be marketed, (ii) determining whether a particular device should be marketed, and (iii) determining what enforcement action, if any, will best serve federal policies and purposes when information required by federal statutes and regulations has not been provided to the federal agency. Such claims also would expose the FDA and other federal agencies to invasive and disruptive civil discovery.

Because the individual States historically have had no role in the formulation, implementation, or enforcement of the federal government's clearance process for medical devices, and because the formulation, implementation, and enforcement of that process historically have been solely within the province of the federal government, no "presumption against preemption" can properly be applied to limit the preemptive effect of the MDA and its implementing regulations. To the contrary, because Respondent's "fraud on the agency" claims could not even have been articulated had Congress not created the FDA, and because such claims would, if allowed, intrude into the decisions, practices, and policies of the FDA, the Supremacy Clause presumes that they cannot be maintained.

ARGUMENT

I. FEDERAL LAW IMPLIEDLY PREEMPTS RESPONDENT'S STATE-LAW "FRAUD ON THE FDA" CLAIMS.

Whether a federal law preempts a state law through the Supremacy Clause, U.S. Const. art. VI, cl. 2, is a question of congressional intent. *Northwest Cent. Pipeline Corp. v. State Corp. Comm'n*, 489 U.S. 493, 509 (1989). "Preemption may be either express or implied, and 'is compelled whether Congress' command is explicitly stated in the statute's language or implicitly contained in its structure and purpose.'" *Fidelity Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 152-53 (1982) (quoting *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977)).

Implied preemption occurs when a state law conflicts with a federal law either because compliance with both would be impossible or because the state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *de la Cuesta*, 458 U.S. at 153. When determining whether a state law stands as an obstacle to the accomplishment of congressional purposes and objectives, courts "examin[e] the federal statute as a whole and identif[y] its purpose and intended effects." *Crosby v. National Foreign Trade Council*, 120 S. Ct. 2288, 2294 (2000). Even if the federal and state laws have common purposes and goals, federal law still preempts state laws that would impair the federal law's methods of achieving those goals: "The fact of a common end hardly neutralizes conflicting means." *Id.* at 2297-98. *Accord International Paper Co. v. Ouellette*, 479 U.S. 481, 494 (1987) ("A state law is also preempted if it interferes with the methods by which the federal statute was designed to reach this goal.").

Under these principles, Respondent's state-law "fraud on the FDA" claims are impliedly preempted both because they would impede the fulfillment of the MDA's purposes and objectives and because they would interfere with the federally selected methods for accomplishing those purposes and objectives. Those claims would contravene Congress's intent not to allow private actions for violations of FDA regulations. They would contravene Congress's intent to have the FDA decide, in accordance with the requirements specified in the MDA, the bases on which applications to market new medical devices should be evaluated and decided. They would contravene Congress's intent to have the FDA decide how and under what circumstances to enforce FDA regulations requiring disclosure of information to the agency. They would undermine the finality of FDA de-

terminations as to which medical devices should be made available to physicians and their patients. And they would subject the FDA and other federal agencies to interference with regulatory tasks by invasive discovery requests from private parties in civil litigation throughout the country.

A. The Court of Appeals' Decision Undermines Congress's Intent Not to Create a Private Right of Action for Violations of FDA Regulations.

In *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996), this Court held that no private right of action exists under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, as amended by the MDA. Accordingly, in its decision below, the court of appeals acknowledged that it is "well established that Congress has not created an express or implied private cause of action for violations of the FDCA or the MDA." Pet. App. 13a. *Accord* Pet. App. 25a. The court emphasized that it did not conclude that "any of the plaintiffs have stated a claim under the FDA's regulations." Pet. App. 25a. Instead, it stated, Respondent's "fraud on the FDA" claims tracked the elements of common-law fraudulent misrepresentation and were "based on state rather than federal law." Pet. App. 9a. As described by the court, common-law fraudulent misrepresentation requires (i) a representation of fact, opinion, intention, or law; (ii) knowledge of its falsity; (iii) intent to induce reliance; (iv) justifiable reliance; and (v) resulting injury. *See* Pet. App. 9a.

Application of those elements to the "fraud on the FDA" claims in this litigation reveals, however, that, even if written as common-law claims, the claims actually constitute an attempt by private parties to seek damages, and impose monetary penalties, for alleged violations of FDA disclosure regulations as interpreted by state courts and juries. The plaintiffs here do not allege that Buckman made any false representation to them or their physicians, and they do not allege that they justifiably relied on any representation by Buckman. *See* Pet. App. 8a-9a. Rather, they allege that their injury resulted from Buckman's alleged deception of the FDA. Thus, as noted by the dissent below, the "fraud on the agency" claims create, in effect, a private right of action for violations of FDA disclosure regulations. *See* Pet. App. 28a (Cowen, J., dissenting).

FDA regulations specify the information that manufacturers must provide in their section 510(k) notifications. *See* 21 C.F.R. § 807.87. The regulations require, among other things, "[p]roposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use." 21 C.F.R. § 807.87(e). Thus, the regulation requires the manufacturer to provide proposed labeling stating the use that will be overtly represented to physicians as the use for which the device is intended. It does not require the manufacturer to submit any separate declaration of any subjective, hoped-for off-label uses that might occur if the FDA should approve the section 510(k) notification and allow the device to be marketed.[2]

The FDCA and the MDA authorize the federal government to enforce, and penalize violations of, their provisions, including provisions that prohibit the making of false or misleading statements to the FDA, the use of false or misleading labeling or advertising, and the failure to provide to the FDA information required by the statutes. *See* 21 U.S.C. §§ 337 (providing for enforcement proceedings by federal government), 331(a)-(b) (prohibiting misbranding of medical devices), 352(a) (defining misbranding to include labeling that "is false or misleading in any particular"), 331(q)(2) (prohibiting submission to FDA of any required report that is "false or misleading in any respect"), 331(w) (prohibiting knowingly false statements to FDA), 352(t)

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[2] The regulations elsewhere provide that the "intended uses of an article may change *after* it has been introduced into interstate commerce," and the labeling must be made adequate for such other uses for a device that has already been "*introduced* into interstate commerce." 21 C.F.R. § 801.4 (emphasis added).

(defining misbranding to include failure "to furnish any material or information required by or under section 360i of this title respecting the device"). The statutes provide the federal government with a wide variety of sanctions and enforcement mechanisms. *See, e.g.*, 21 U.S.C. §§ 333(a) (criminal penalties), 332 (injunctions), 333(f)(1) (civil monetary penalties), 334 (seizure), 360h(e) (recall), 360e(e)(C) (withdrawal of approval to market, if "the application contained or was accompanied by an untrue statement of a material fact").

Congress made clear its intent that enforcement of these laws must be by the federal government: "Except as provided in subsection (b) of this section, all such proceedings for the enforcement . . . of this chapter shall be by and in the name of the United States." 21 U.S.C. § 337(a). Congress could have included in the exceptions a provision allowing private rights of action for fraud on the FDA, but it did not do so. *See* 21 U.S.C. § 337(b).

Respondent's "fraud on the FDA" claims conflict with this extensive statutory scheme. Though purporting to be state-law fraud claims, they in fact depend entirely on alleged violations of federal statutes and regulations requiring that certain information be disclosed to the FDA. Respondent concedes as much in its brief in opposition to the petition for a writ of certiorari:

> The basis for plaintiffs' fraud claim is that Buckman and others defrauded the FDA by making false statements to the agency concerning an issue of paramount *regulatory concern* – the intended use of AcroMed orthopedic plates and screws. Thus, *plaintiffs seek recovery for conduct which violates federal law*.

Brief in Opposition to Petition for a Writ of Certiorari 18 (emphasis added). If Congress had not created the FDA, and if the FDA had not promulgated its regulation requiring manufacturers to submit "[p]roposed labels, labeling, and advertisements sufficient to described the device, its intended use, and the directions for its use," it would have been literally impossible for plaintiffs

to have alleged this "fraud on the FDA" claim. Allowing such a claim, therefore, would not preserve any historically available state-law claim. Instead, it would grant plaintiffs a new private right of action based solely on federal regulations promulgated and enforced by a federal agency to promote federal purposes and objectives.

Moreover, unlike the sweeping preemption rejected by this Court in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), preemption of "fraud on the FDA" claims such as those asserted by Respondent here would not bar "most, if not all, relief for persons injured by defective medical devices." *Id.* at 487. To the contrary, disallowing a private action seeking monetary relief based on alleged violations of FDA disclosure regulations would not prevent any person injured by a defective or mislabeled device from seeking redress under any of several traditional state-law theories. *Lohr* instructs, for example, that plaintiffs may pursue state-law claims based on design defects, manufacturing defects, or inadequate warnings. 518 U.S. at 494, 501-02. They also may seek relief for fraudulent statements allegedly made to themselves or their physicians, or for claims based on breaches of express and implied warranties.

Although not a "fraud on the FDA" case, *Chicago & North Western Transportation Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311 (1981), is instructive because it focuses on the disruption to agencies that private, state-law tort claims can cause. The Court there considered whether a state-law damages action "may be asserted against a regulated carrier when the [Interstate Commerce] Commission has approved its decision to abandon the [railroad] line in question." 450 U.S. at 313. The Court observed that the Commission's authority to decide whether to allow carriers to abandon existing railroad lines was "critical to the congressional scheme, which contemplates comprehensive administrative regulation of interstate commerce," and "[i]n deciding whether to permit an abandonment, the Commission must balance 'the interests of those now served by the present line

on the one hand, and the interests of the carrier and the transportation system on the other.'" *Id.* at 321 (citation omitted). The Court concluded that the agency's determinations were not susceptible to judicial "redecision" because "[t]he breadth of the Commission's statutory discretion suggests a congressional intent to limit judicial interference with the agency's work." *Id.* The Court therefore held that state-law damages actions were impliedly preempted because they would, if allowed, conflict with federal purposes. *Id.* at 326.

Here, as in *Kalo Brick*, (i) the FDA's authority to decide whether, and based on what information, to allow new medical devices to be marketed is "critical to the congressional scheme"; (ii) in deciding whether to permit a new device to be marketed, the FDA must balance the need to ensure safety with the interests of patients who will benefit from greater availability of, and lower prices for, medical devices that otherwise would be restricted to "grandfathered" devices with little or no competition; and (iii) the breadth of the FDA's rulemaking and enforcement powers, combined with Congress's clear intent to preclude private causes of action, "suggests a congressional intent to limit judicial interference with the agency's work." State-law actions that not only second-guess the FDA's decisions, but do so based on a theory that the FDA should have received additional information and would have reached a different decision had it received the additional information, constitute the type of "interference with the agency's work" that *Kalo Brick* held must be preempted.

Because the "fraud on the FDA" claims asserted by Respondent conflict with Congress's intent not to create a private right of action under the MDA, and would interfere with Congress's method of giving the FDA authority to decide what actions to take if required information has not been provided, those claims are preempted by the MDA and its implementing regulations.

B. Respondent's State-Law "Fraud on the FDA" Claims Would in Effect Alter the Disclosure Requirements Established by the FDA for Section 510(k) Notifications.

The FDA reviewed Buckman's section 510(k) notification materials, found that they provided the information required by the MDA and its implementing regulations, and determined that the devices could lawfully be marketed. *See* Pet. App. 5a. Respondent's "fraud on the FDA" claims attempt to override those FDA decisions. Respondent's claims ask state courts and juries to conclude that Buckman should have provided the FDA with information about the manufacturer's alleged subjective hope that, despite the approved, uniform statements of intended use on the devices' labeling and advertising, the entire orthopedic community would put the devices only to off-label uses. Those claims also ask state courts and juries to conclude that, if Buckman had stated such a subjective hope, the FDA would not have allowed the devices to be marketed in competition with the "grandfathered" devices to which the FDA found the new devices "substantially equivalent." Under Respondent's theory, if any court or jury so concludes, the manufacturer may be liable in damages, even though (i) the FDA approved the application, (ii) the FDA has not found the devices to be mislabeled, (iii) the FDA subsequently reviewed evidence submitted by Respondent and stated that the FDA "does not believe that pedicle screw spinal systems present a substantial deception or an unreasonable and substantial risk of illness or injury," 63 Fed. Reg. 40025, 40035-36 (July 27, 1998), and (iv) Respondent has not alleged that the devices are defective, unreasonably dangerous, or mislabeled, or that any false or misleading statement was made to plaintiffs or their physicians.

If the decision below stands, device manufacturers submitting subsequent 510(k) notifications to the FDA will tend not to provide the FDA only with information the FDA itself requires; rather, manufacturers will be induced to try to predict what

courts and juries in the various States might in later years decide the FDA should have been provided and would have considered dispositive if the information had been provided. Manufacturers will likely burden the FDA with information they think juries might some day decide the FDA should have been provided, regardless of whether the FDA in fact required that information.

The pertinent regulation governing section 510(k) notifications, 21 C.F.R. § 807.87, did not require disclosure of the manufacturer's subjective intent regarding how it hoped physicians might use its device off-label. Even the regulation governing post-clearance developments, 21 C.F.R. § 801.4, defined "intended uses" as "the *objective intent* of the persons legally responsible for the labeling of devices." 21 C.F.R. § 801.4 (1985) (emphasis added). That post-clearance intent "is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article." *Id.* A device's intended uses "may change after it has been introduced into interstate commerce by its manufacturer"; if they do, the seller "is required to supply adequate labeling in accordance with the new intended uses." *Id.* Thus, even the post-clearance regulation focuses on the applicant's initial "objective intent," recognizes that "intended uses" may change over time as a manufacturer gains knowledge, rather than speculative hopes, about *actual* use in the medical community, and requires corresponding changes in the labeling under those circumstances.

The MDA prohibits manufacturers from advertising or otherwise marketing devices for off-label uses. *See* 21 U.S.C. §§ 321(n), 331(a)-(b). It authorizes the FDA to enforce that prohibition by, among other actions, withdrawing its clearance for marketing of a device if the manufacturer markets the device for an off-label use. *See* 21 U.S.C. § 360e(e). The FDA may require additional labeling if it determines that a manufacturer's devices are being used off-label in a manner that requires such additional labeling. *See* 21 C.F.R. § 801.4. Neither the MDA nor its implementing regulations contain a provision, however,

for the agency to withdraw its marketing clearance if it should learn that, when the manufacturer submitted its section 510(k) notification, the manufacturer harbored a subjective hope or belief that physicians would put the device only to off-label uses once the device received marketing clearance from the FDA.

Accordingly, Plaintiffs' "fraud on the FDA" claims would alter the FDA's definition of "intended use" for section 510(k) notifications, alter the section 510(k) notification requirements, and undermine the FDA's decisions as to which medical devices should be allowed on the market and with what labeling. The claims would use state law to penalize conduct that federal law permits. *Cf. Crosby v. National Foreign Trade Council*, 120 S. Ct. 2288, 2296-97 (2000) (noting that the challenged state statute "conflicts with the federal law at a number of points by penalizing individuals and conduct that Congress has explicitly exempted or excluded from sanctions," and holding the state law preempted).

Such state-law revisions of federal requirements would endanger federal objectives and create substantial uncertainties in the approval process. The decision below, for example, emphasizes that Respondent's representative complaint alleges that the manufacturer subjectively intended the device to be "exclusively for use in the spine" when they filed their section 510(k) notification. Pet. App. at 8a. Under that rationale, could a "fraud on the agency" claim likewise proceed if a manufacturer secretly hoped or believed that 90%, rather than 100%, of post-clearance sales of a new medical device would be for off-label use in spinal surgery? Would a hope or belief of 50% suffice to state a claim? Would it make any difference if the manufacturer subjectively hoped or believed that the off-label use would be minimal at first, but build over a period of time? Would it make any difference if, when the manufacturer filed its section 510(k) notification, it subjectively hoped or believed that off-label uses would occur post-clearance, but it changed its mind before clearance was granted? If it changed its mind the day after

clearance was granted? Would federal policies and purposes be rationally served by allowing "fraud on the agency" claims if the subjective intent was formed one week before clearance was granted, but not if the subjective intent was formed one week after clearance was granted, especially if, as here, there is no claim that the device is defective, unreasonably dangerous, or mislabeled?

If there is to be a disclosure requirement pertaining to some subjective intent at the time a section 510(k) notification is filed, all of these are questions that the federal agency charged by Congress with the responsibility for promulgating and enforcing the regulations, not courts and juries in all the States, should answer. The agency knows what information it needs and wants, and its decision should not be displaced by a hodgepodge of decisions by state courts and juries. The agency knows what information is important enough to warrant enforcement proceedings, or an order requiring labeling changes, when information it requires is withheld or misrepresented. And the agency knows what balance it seeks to strike between ensuring informed decision-making and imposing penalties that might impair competition, cause the public to be deprived of certain products, cause the prices of medical devices to increase, or induce regulated entities to burden the agency with unwanted information in order to avoid such penalties in the future.

The agency is also uniquely capable of promulgating uniform standards. State-imposed disclosure requirements would vary, not only because jury verdicts would differ, but also because state-law fraud doctrines are not uniform. Because of differences in substantive state fraud laws, device manufacturers, if threatened with state-law "fraud on the agency" claims, would tend not only to satisfy the FDA's requirements for section 510(k) applications, but also to survey state laws and submit to the FDA materials that courts and juries in any of the 50 states might conclude should be submitted to the FDA.

For these reasons, state-imposed requirements penalizing manufacturers with damages awards in private actions for not disclosing their subjective hopes when section 510(k) notifications are filed would impermissibly conflict with the federally selected method of introducing new devices to the market. *See International Paper Co. v. Ouellette*, 479 U.S. 481, 494 (1987) ("[I]t is not enough to say that the ultimate goal of both federal and state law is [the same]. A state law also is pre-empted if it interferes with the methods by which the federal statute was designed to reach this goal."). As the United States has noted, "[D]uties concerning the submission of information to a federal agency are, at least as a general matter, appropriately defined and enforced by the federal government." Brief for the United States as *Amicus Curiae* in Support of the Petition 15. State courts and juries should not be permitted to substitute their own varying views of disclosure requirements for the uniform requirements that the FDA has promulgated to promote federal purposes and objectives.

C. The Decision Below Would Upset the FDA's Balance Between Keeping Unsafe or Ineffective Devices off the Market and Allowing Physicians to Use Devices for Innovative Off-Label Purposes.

The FDA neither controls the practice of medicine nor interferes with physicians' judgment about how to use a lawfully marketed device. In a statement to a House subcommittee, Michael Friedman, the FDA's Deputy Commissioner for Operations, testified:

> The history of the FDC Act indicates Congress did not intend FDA to interfere with the practice of medicine. Thus, once a product is approved for marketing for a specific use, FDA generally does not regulate how, and for what uses, physicians prescribe that drug.... FDA recognizes that, in certain circumstances, off label uses of approved products are appropriate, rational, and accepted medical practice. Off label uses, particularly for oncology, rare diseases, and

> pediatrics, can be of great value. Some off label uses have been of great historical importance. Use of beta blockers in hypertension and angina preceded labeling for these uses by many years. It is inevitable that there will be preliminary support for off label uses before definitive information becomes available. Physicians confronted with patient needs, may choose to act on such data, especially where there are no good alternatives.

Michael Friedman, *Misuse of Prescription Drugs*, Statement to the Subcommittee on Human Resources and Intergovernmental Relations Committee on Government Reform and Oversight, 1996 WL 10830744, at *5 (Sept. 12, 1996).

The FDA has recognized the importance of physicians' ability to use prescription medical products off-label: "Such 'unapproved' or, more precisely, 'unlabeled' uses may be appropriate and rational in certain circumstances, and may in fact, reflect approaches to drug therapy that have been extensively reported in medical literature." *Use of Approved Drugs for Unlabeled Indications*, 12 FDA Drug Bulletin 4 (Apr. 1982). The American Medical Association estimates that 40 to 60 percent of all prescriptions in the United States are written for drugs to be used for a purpose other than their FDA-approved purpose. Veronica Henry, *Off-Label Prescribing: Legal Implications*, 20 J. Legal Med. 365, 365 (1999) (citation omitted). Indeed, in some fields of medicine, off-label use has become the standard of care. In 1995, for example, the FDA recognized that, since 1992, pedicle fixation with bone screws had constituted the standard of care in the surgical community. *See Proposed Rules: Orthopedic Devices: Classification, Reclassification, and Codification of Pedicle Screw Spinal Systems*, 60 Fed. Reg. 51946, 51947 (1995). In short, off-label uses of medical devices are a "valuable part of the practice of medicine." Pet. App. 29a (Cowen, J., dissenting).

The FDA is well aware of its duties regarding the possible harm resulting from off-label uses. It has established strict requirements to prevent companies from using marketing practices to promote off-label uses. *See, e.g.*, 21 U.S.C. § 360aaa. If a manufacturer wants to market a device for what is currently an off-label use, the manufacturer must apply for FDA approval to market for that use. *See* 21 U.S.C. § 360e(d)(6)(A); Friedman, *Misuse of Prescription Drugs*, 1996 WL 10830744, at *7-8. And, as already noted, the FDA's regulations require that if, after a device has been introduced into interstate commerce, it is used for purposes other than the ones for which the manufacturer offers it, the manufacturer must "provide adequate labeling for such a device which accords with such other uses . . . ." 21 C.F.R. § 801.4. The FDA thus has struck the balance it has concluded is necessary to ensure the safety and effectiveness of medical devices and to foster appropriate innovative uses of those devices by physicians.

Respondent seeks to use state tort laws to impose a different balance. Specifically, Respondent seeks to make the balance turn not on the objective factors of (i) the use stated in the device's labeling, (ii) uses to which the device is actually put once on the market, and (iii) the device's safety and effectiveness for those uses as determined by the FDA's experts, but instead on the subjective question of whether, when the manufacturer submitted its 510(k) notification, the manufacturer harbored a hidden hope that the device would be used exclusively for an off-label purpose. Then, Respondent seeks to use state tort laws in private lawsuits to impose monetary penalties, collected by private plaintiffs, not because the device was defective or unreasonably dangerous when put to the off-label use, and not because the device was mislabeled in a manner on which plaintiffs or their physicians relied, but simply because the manufacturer did not initially disclose its subjective intent to the FDA.

Respondent's state-law "fraud on the FDA" claims would thus impair the FDA's method and goal of striking a balance between ensuring the safety and effectiveness of medical devices and not unduly restricting the medical community's inno-

vative uses of medical devices in the exercise of physicians' medical judgment. For that reason, such claims are impliedly preempted.

D. Respondent's "Fraud on the FDA" Claims Would Expose the FDA to Burdensome Discovery in Private Litigation Throughout the Country.

The decision below also would interfere with the FDA's purposes, objectives, and methods by subjecting the agency to discovery requests by private litigants asserting "fraud on the FDA" claims. Such discovery requests would intrude into the FDA's deliberations and decisions and divert the agency's attention and resources from the task of performing regulatory functions to the task of responding to discovery requests.

Nor would the FDA be the only federal agency subject to such intrusions and diversions. Under Respondent's theory, any federal agency responsible for regulating an industry would be vulnerable to a flood of discovery requests in private lawsuits in which plaintiffs assert "fraud on the agency" claims against the regulated entities.

The burden on federal agencies could be substantial. Plaintiffs are likely to seek discovery to prove (i) that the agency intended its regulations to mean what the plaintiffs contend they mean, (ii) that the agency relied on the allegedly fraudulent statement, and (iii) that the agency would have taken some different action with respect to the device had it received the information the plaintiffs claim it should have received. Defendants are likely to seek additional discovery to prove (iv) that the agency did not intend to require the information that plaintiffs contend was fraudulently withheld, (v) that, whatever the agency's intent, the agency did not consider the information material to safety determinations, and (vi) that the agency would not have taken any different action had it received the information the plaintiffs claim it should have received. In this case, for

example, defendants would want to obtain from the FDA all agency documents showing that FDA officials knew and understood, from their review of the defendants' previous section 510(k) filings, that the defendants hoped physicians would use the device "off-label" for spinal fixation surgery, that the "grandfathered" devices on which the defendants' section 510(k) notifications were based had been used off-label in numerous instances for spinal fixation, and that agency officials knew of the prevalence of such off-label uses.

The burden of responding to such discovery requests – even if the agency's responses were repeated refusals to produce documents or deponents – could be substantial. This multidistrict litigation alone, for example, involves more than 2,000 individual actions that may be tried in various jurisdictions. *See* Pet. App. 1a. And this litigation involves only orthopedic screws. If the likely discovery here were to be multiplied by the number of other medical devices or drugs that could become the subject of "fraud on the FDA" actions, and by the number of potential lawsuits alleging fraud on other federal agencies, the draining of agency resources, diversion of agency attention from regulatory duties, and alteration of internal decision-making processes would be staggering.

In sum, "fraud on the FDA" claims would obstruct congressional objectives in several ways. They would impose new disclosure requirements on section 510(k) notifications, burdening the FDA with information it did not want. They would alter manufacturers' behavior in submitting materials to the FDA and proposing devices for marketing as "substantially equivalent" to predicate devices. They would impair the FDA's chosen method of balancing physicians' innovative off-label uses against the need to ensure the safety and efficacy of marketed devices. And they would expose federal agencies to repeated, burdensome civil discovery that interferes with the agencies' regulatory functions. Because "fraud on the FDA" claims would erect these obstacles to the achievement of federal pur-

poses and objectives, and interfere with the methods chosen by Congress and the FDA to achieve those purposes and objectives, they are impliedly preempted.

II. BECAUSE THE REGULATION OF MEDICAL DEVICES IS NOT WITHIN THE STATES' HISTORICAL POLICE POWERS, NO PRESUMPTION AGAINST PREEMPTION SHOULD APPLY TO THIS CASE.

In summarizing its reasons for concluding that Respondent's "fraud on the FDA" claims survived preemption, the court of appeals below relied on a "presumption against preemption." Pet. App. 18a. It erred in doing so. Although this Court has applied a presumption against preemption in some circumstances, no such presumption can properly be applied here, where the federal government has a strong and well-established interest in uniform regulation and the regulation in question has not historically fallen within the States' police powers.

This Court's articulation of a presumption against preemption of state law has occurred primarily in cases "in which Congress has 'legislated . . . in a field which the States have traditionally occupied . . . .'" *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (quoting, *inter alia*, *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). *Accord CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 664 (1993); *Pacific Gas & Elec. Co. v. State Energy Resources Conservation & Dev. Comm'n*, 461 U.S. 190, 206 (1983). In other contexts the Court often has conducted its preemption analysis without employing the presumption at all. *See Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 545-46 (1992) (Scalia, J., concurring in the judgment in part and dissenting in part) (citing *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 383 (1992), and *Norfolk & W. R.R. Co.*

v. American Train Dispatchers Ass'n, 499 U.S. 117, 129 (1991)).[3]

The Court's recent preemption decisions show the limited applicability of such a presumption. In *United States v. Locke*, 120 S. Ct. 1135, 1147-48 (2000), the Court construed the presumption narrowly, stating that "an 'assumption' of nonpreemption is not triggered when the State regulates in an area where there has been a history of significant federal presence." One month later the Court applied no such presumption before concluding that federal railroad statutes and regulations preempted a state wrongful-death action. *Norfolk S. Ry. Co. v. Shanklin*, 120 S. Ct. 1467 (2000). Still more recently the Court held, without applying any presumption against preemption, that federal law preempted the plaintiffs' state-law tort claim. *Geier v. American Honda Motor Co.*, 120 U.S. 1913 (2000). And in *Crosby v. National Foreign Trade Council*, 120 S. Ct. 2288 (2000), the Court indicated that the presumption is unnecessary in an "obstacle preemption" case: "Assuming, arguendo, that some presumption against preemption is appropriate, we conclude, based on our analysis below, that the state Act presents a sufficient obstacle to the full accomplishment of Congress's objectives under the federal Act to find it preempted." *Id.* at 2294 n.8. These decisions confirm that the presumption against pre-

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[3] Cases other than those cited by Justice Saclia in *Cipollone* in which the Court disregarded any presumption against preemption abound. *See, e.g., American Airlines, Inc. v. Wolens*, 513 U.S. 219 (1995); *FMC Corp. v. Holliday*, 498 U.S. 52 (1990); *Louisiana Pub. Serv. Comm'n v. Federal Communications Comm'n*, 476 U.S. 355 (1986); *Allis-Chalmers Corp. v. Lueck*, 471 U.S. 202 (1985); *Brown v. Hotel & Restaurant Employees & Bartenders Int'l Union Local 54*, 468 U.S. 491 (1984); *Capital Cities Cable, Inc. v. Crisp*, 467 U.S. 691 (1984); *Fidelity Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141 (1982); *Malone v. White Motor Corp.*, 435 U.S. 497 (1978); *United States v. Shimer*, 367 U.S. 374 (1961); *McDermott v. State of Wisconsin*, 228 U.S. 115 (1913).

emption is narrow in scope and must be closely cabined to prevent it from undermining the mandate of the Supremacy Clause.

The presumption is especially inapplicable here. This case focuses on the scope and enforcement of *federal* regulations pertaining to medical devices – an area firmly under the control of a federal agency and subject to an extensive federal regulatory scheme. *Cf. Locke*, 120 S. Ct. at 1148 (noting Congress's historical legislation of maritime commerce and its "extensive federal statutory and regulatory scheme," and declining to apply an assumption of non-preemption). Not only are the scope and enforcement of federal regulations historically in an "area where there has been a history of significant federal presence," *id.* at 1147-48, but the individual States have had no historical role whatsoever in regulating what information is required to be provided to the FDA, and no such area has been "traditionally occupied" by the States. *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). The history of federal presence and the lack of state involvement dictate that no presumption against preemption can properly be applied here.

A presumption against preemption is further inapplicable because of the established principle that state law must yield to federal law when, as here, a state law does interfere with federal law. As this Court has stated:

> The relative importance to the State of its own law is not material when there is a conflict with a valid federal law, for the Framers of our Constitution provided that the federal law must prevail. Article VI, Clause 2. This principle was made clear by Chief Justice Marshall when he stated for the Court that *any state law, however clearly within a State's acknowledged power, which interferes with or is contrary to federal law, must yield.*

Free v. Bland, 369 U.S. 663, 666 (1962) (emphasis added)(quoted with approval in *Fidelity Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 153 (1982)); *Brown v. Hotel & Restaurant Employees & Bartenders Int'l Union Local 54*, 468

U.S. 491, 503 (1984); *Gade v. National Solid Wastes Mgt. Ass'n*, 505 U.S. 88, 108 (1992) (plurality opinion) (even if a State has a "compelling interest," the Supremacy Clause requires that "any state law . . . clearly within a State's acknowledged power, which interferes with or is contrary to federal law, must yield"). Indeed, the Court has applied what amounts to a presumption *in favor of* preemption in cases where the interest in federal primacy and uniformity is well-established. *See, e.g., Hines v. Davidowitz*, 312 U.S. 52, 63, 68 (1941) (foreign relations and regulation of aliens); *Allen-Bradley Local No. 1111 v. Wisconsin Employment Relations Bd.*, 315 U.S. 740, 749 (1942) (same); *cf. Brown*, 468 U.S. at 502-503 (recognizing "presumption of federal preemption" in areas within the primary jurisdiction of the NLRB). This reflects the common-sense conclusion that, in a field long and thoroughly dominated by federal statutes and interests, Congress is unlikely to enact statutes that allow state laws to intrude on and conflict with the purposes and methods of the federal statutes.

Even when a State's tort law is advanced as a means of exercising the States' historical police power to safeguard their citizens' health or safety, it cannot save from preemption a state-imposed duty that conflicts with a federally-imposed duty. In *Boyle v. United Technologies Corp.*, 487 U.S. 500, 509 (1988), the Court noted that a state-imposed duty of care regarding the design of a product would conflict with the design duty imposed on the manufacturer under its contract with the federal government. The state-law duty undeniably concerned a critical issue of health and safety – namely, whether a pilot's family could recover damages from a helicopter manufacturer after a design defect in a helicopter's escape hatch allegedly caused the pilot's death. Nonetheless, the Court held the state tort claim preempted. *Id.* at 511-12.

Accordingly, this is not a proper case in which to apply a presumption against preemption. Even if the Court were to consider such a presumption, the presumption could not prevent

preemption here, because the federal government historically has determined the scope and enforcement of its own regulations regarding the information to be provided to the FDA, and this area of law does not implicate any historical police power of the States.

CONCLUSION

Because federal law preempts Respondent's state-law "fraud on the FDA" claims, the judgment of the court of appeals should be reversed.

Respectfully submitted,

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No. 98-1768

IN THE

Supreme Court of the United States

THE BUCKMAN COMPANY,
Petitioner,

v.

PLAINTIFFS' LEGAL COMMITTEE,
Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Third Circuit

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BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

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QUESTIONS PRESENTED

1. Whether a state tort claim collaterally attacking a decision of the Food and Drug Administration to permit the marketing of a medical device on the ground that approval was obtained through a "fraud on the agency" is expressly or impliedly preempted by the Medical Device Amendments to the Federal Food, Drug and Cosmetic Act.

2. Whether the Medical Device Amendments, which expressly preempt "any" state requirement that "relates to the safety or effectiveness" of a device and is "different from, or in addition to" a federal requirement (21 U.S.C. § 360k(a)), exclude state requirements that are imposed through tort laws of general applicability.

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BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

INTERESTS OF *AMICUS CURIAE*

The Washington Legal Foundation (WLF) is a Washington, D.C.-based nonprofit public interest law firm with supporters in all 50 states.[1] WLF devotes a significant portion of its resources to promoting economic liberty, free

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[1] Pursuant to S. Ct. R. 37.6, WLF hereby affirms that no counsel for either party authored any part of this brief, and that no person or entity, other than WLF, its supporters, and its counsel, made a monetary contribution to the preparation or submission of this brief.

enterprise principles, and a limited and accountable government.

To that end, WLF has appeared before this and other state and federal courts in cases involving preemption issues, seeking to point out the economic inefficiencies created when multiple levels of government seek simultaneously to regulate the same business activity. *See, e.g., Geier v. American Honda Motor Co.*, 120 S. Ct. 1913 (2000); *United States v. Locke*, 120 S. Ct. 1135 (2000); *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996). WLF is particularly concerned that the American economy suffers, and public safety or health can be jeopardized, when state law, including state tort law, imposes upon industry an unnecessary layer of regulation that obstructs or frustrates the objectives or operation of specific federal regulatory regimes, such as the Medical Device Amendments ("MDA") to the Federal Food, Drug and Cosmetic Act ("FDCA") at issue here.

WLF also believes that medical consumers are best served by the widest possible dissemination of truthful information about FDA-approved product, even when that truthful information relates to off-label uses of the products. WLF successfully challenged, on First Amendment grounds, FDA efforts to suppress dissemination of such information. *Washington Legal Found. v. Henney*, 56 F. Supp. 2d 81 (D.D.C. 1999), *appeal dism'd*, 202 F.3d 331 (D.C. Cir. 2000). WLF is concerned that if suits such as Respondent's are determined not to be preempted by federal law, manufacturers will be reluctant to employ methods permissible under federal law for disseminating such information.

WLF fully concurs with Petitioner's argument that Respondent's claims are impliedly preempted. WLF is filing separately in order to focus on arguments that those claims are also expressly preempted by virtue of 21 U.S.C. § 360k(a). In particular, WLF's brief focuses on the type of federal "requirement" that must be present in order for § 360k(a) preemption to apply.

WLF submits this brief in support of Petitioner with the written consent of all parties. Letters providing blanket consent to all *amicus curiae* briefs are on file with the Clerk of the Court.

STATEMENT OF THE CASE

In the interests of brevity, WLF hereby adopts by reference the Statement contained in Petitioner's Brief.

In brief, this case involves state-law personal injury suits filed by numerous plaintiffs who claim to have suffered injury after having orthopedic bone screws implanted into the pedicles of their spines. Those suits were consolidated for pre-trial proceedings pursuant to the multi-district litigation statute, 28 U.S.C. § 1407. Many of the suits claim that one defendant, Petitioner Buckman Company ("Buckman"), induced the Food and Drug Administration ("FDA") to permit the marketing of the bone screws by means of a series of fraudulent misrepresentations. The suits claim that had Buckman not defrauded FDA, the bone screws never would have been marketed in this country, doctors would not have been able to use the bone screws in their surgery, and thus the plaintiffs never would have been injured.

Buckman is a regulatory consultant to medical device manufacturers; it was retained by AcroMed Corporation to act as its liaison with FDA in its attempt to secure marketing clearance for its orthopedic bone screw device, known as VSP, for which AcroMed sought approval for use in back surgery. Buckman initially was unsuccessful in its efforts to secure marketing clearance under the "§ 510(k)" process -- which permits marketing of medical devices shown to be substantially equivalent to a device already on the market when the MDA was adopted in 1976. In December 1985, Buckman altered its approach. It split the VSP into two components and filed a separate § 510(k) application for each component. In each application, a new "intended use" was specified: the applications sought approval for use of the two components in the long bones of the arms and legs rather than in the pedicles of the spine. Respondent Plaintiffs' Legal Committee, representing all plaintiffs in the multi-district litigation, claims that the December 1985 applications were fraudulent because Buckman and AcroMed intended that the two components be used *solely* in the pedicles of the spine. FDA approved the applications; Respondent contends that FDA would not have done so had it been aware of Buckman and AcroMed's actual intended use.

Buckman and other defendants sought judgment on the pleadings on all such "fraud on the FDA" claims on the ground that those claims were expressly preempted by § 521(a) of the MDA, 21 U.S.C. § 360k(a), which prohibits States from imposing "any requirement" "with respect to" a medical device which is "different from, or in addition to, any requirement applicable under [the FDCA] to the device." The district court granted the motion on March 2, 1995. Petition Appendix ("Pet. App.") 46a-53a. The court

held that "fraud on the FDA" claims were both expressly preempted by § 360k(a) and impliedly preempted by the entire federal enforcement scheme, which vests in FDA exclusive authority to prosecute violations of the MDA. *Id.* at 48a-50a.

The following year, this Court rendered its decision in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), which addressed the scope of § 360k(a). Respondent thereafter asked the district court to reconsider its March 2, 1995 dismissal order in light of *Medtronic*. On March 28, 1997, the district court reaffirmed the dismissal. Pet. App. 33a-44a. While acknowledging that *Medtronic* had undercut a portion of its analysis, the court adhered to its view that "fraud on the FDA" claims had been impliedly precluded by Congress when it decided not to provide for a private right of action to enforce the MDA. *Id.* at 40a. Because the "fraud on the FDA" claim was Respondent's only claim against Buckman, the district court entered final judgment for Buckman, and Respondent appealed therefrom.

The Third Circuit reversed by a 2-1 vote. Pet. App. 1a-32a. The appeals court held that § 360k(a) was inapplicable to "fraud on the FDA" claims because the § 510(k) approval process to which the AcroMed bone screws were subjected established no federal "requirement" "applicable to a device" and because Respondent's suit did not seek to impose a State "requirement" "with respect to" the bone screws. *Id.* at 13a. The appeals court also rejected Buckman's implied preemption claims, stating, "We see no inconsistency between the FDA having the exclusive prerogative of bringing actions to enforce the FDCA and preserving the right of people in the plaintiffs' position to bring common law fraudulent misrepresentation claims." *Id.* at 18a.

Judge Cowen dissented. *Id.* at 25a-32a. He noted that Respondent's claim was not dependent on a showing that the information Buckman or AcroMed submitted in order to demonstrate that the products were entitled to § 510(k) "long bone" marketing approval was false, or that they ever actually marketed bone screws for use in back surgery. *Id.* at 25a-26a. He stated that, under the majority's holding, the only basis for finding that Buckman/AcroMed committed fraud on the FDA was that they allegedly intended (*after* obtaining § 510(k) clearance) to violate FDA prohibitions on off-label promotion. *Id.* at 27a-28a. He charged that such a holding was equivalent to creating a private right of action to enforce those regulations -- even though Congress clearly did not intend to create such a right of action. *Id.* He also stated that the decision was likely to prevent doctors from obtaining valuable and potentially life-saving information about off-label uses of FDA-approved products. *Id.* at 28a-32a.

SUMMARY OF ARGUMENT

Respondent's "fraud on the FDA" claim is expressly preempted by § 360k(a). By its terms, § 360k(a) is applicable where: (1) there exists an applicable *federal* "requirement" of the type contemplated by § 360k(a)(1); (2) there exists a *State* "requirement" of the type contemplated by § 360k(a); and (3) the State "requirement" is "different from or in addition to" the applicable federal requirement. Buckman has demonstrated that all three of those conditions exist.

The Third Circuit's findings to the contrary were based on a misreading of *Medtronic*. The Third Circuit interpreted *Medtronic* as *mandating* that those three findings go against

Buckman. In fact, *Medtronic* took a much more nuanced approach and carefully considered the effect of § 360k(a) on each of the claims at issue there. Respondent's "fraud on the FDA" claim was not one of the causes of action in *Medtronic*. If one applies the approach taken in *Medtronic* to this case, one is compelled to conclude that the "fraud on the FDA" claim is expressively preempted by § 360k(a). Perhaps of greatest significance is that Respondent's cause of action, far from simply providing a parallel mechanism for disciplining those guilty of fraud, undermines the federal government's significant interest in the finality of its own administrative determinations.

Finally, WLF wishes to call the Court's attention to the history of FDA enforcement of § 360k(a). That history provides an explanation regarding how the "specific counterpart regulations" language worked its way into 21 C.F.R. § 808.1(d), an FDA regulation that purports to explain §360k(a). The history suggests that the Court gave § 808.1(d) an overly restrictive reading in *Medtronic*; the Court should take this opportunity to clear up any misunderstanding and to explain that § 808.1(d) does *not* impose strict limits on the types of federal "requirements" that can give rise to § 360k(a) preemption.

ARGUMENT

I. PREEMPTION OF STATE TORT LAW IS ULTIMATELY AN ISSUE OF CONGRESSIONAL INTENT, AND CONGRESS EXPRESSED AN INTENT TO PREEMPT STATE TORT LAW WHEN IT ADOPTED § 360k(a)

Whether the federal government has preempted an assertion of regulatory authority by state or local governments in a given instance is ultimately an issue of the intent of Congress and the operation of the Supremacy Clause. As the Court has repeatedly emphasized, "Pre-emption fundamentally is a question of congressional intent . . . ." *English v. General Electric Co.*, 496 U.S. 72, 78-79 (1990). *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992) ("'[t]he purpose of Congress is the ultimate touchstone' of preemption analysis") (quoting *Malone v. White Motor Corp.*, 435 U.S. 497, 504 (1978)); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 486-87 (1996) ("any understanding of the scope of a pre-emption statute must rest primarily on 'a fair understanding of *congressional purpose.*'") (emphasis in original) (quoting *Cipollone*, 505 U.S. at 530 n.27 (opinion of Stevens, J.)).

In other words, it is the role of Congress, not a court, to define how broad or narrow a federal statute's preemptive reach should be. Of course, the courts look to a variety of sources[2] and employ a variety of interpretive techniques in

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[2] "Congress' intent, or course, primarily is discerned from the language of the pre-emption statute and the 'statutory framework' surrounding it." *Medtronic*, 518 U.S. at 486 (quoting *Gade v. Nat'l* (continued...)

attempting to discern what Congress intended.[3] But once Congress's preemptive intent has been identified, it is not the role of the courts to construe preemption provisions broadly or narrowly. A court's "task in all pre-emption cases is to enforce the 'clear and manifest purpose of Congress.'" *Gade*, 505 U.S. at 111 (Kennedy, J., concurring in part and concurring in the judgment) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

Congress's intent to preempt state and local law may be explicitly stated in its statutory language or implicitly contained in the statute's structure or purpose. *Cipollone*, 505 U.S. at 516. State law is impliedly preempted if: (1) it actually conflicts with federal law; or (2) federal law so thoroughly occupies a legislative field "as to make reasonable the inference that Congress left no room for the

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[2](...continued)
Solid Wastes Management Ass'n, 505 U.S. 88, 111 (1992) (Kennedy, J., concurring in part and concurring in the judgment)).

[3] When the challenged State action is in a field that the States have traditionally occupied, such as "the historic police powers of the States," the Court generally has begun its analysis of congressional intent with the "assumption" that Congress would not seek to supplant the exercise of such traditional powers "unless that was the clear and manifest purpose of Congress." *Medtronic*, 518 U.S. at 485. That "presumption against preemption" has no place in this case, because States have not historically sought to regulate the relationship between the business community and federal regulatory agencies generally, or FDA in particular; that relationship has generally been governed principally or exclusively by federal law. *See United States v. Locke*, 120 S. Ct. 1135, 1147 (2000) ("an 'assumption' of nonpreemption is not triggered when the State regulates in an area where there has been a history of significant federal presence.").

States to supplement it." *Id.* (citations omitted). State law "actually conflicts" with federal law "*either* because compliance with both federal law and state regulations is a physical impossibility, *or* because the state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *California Fed. Sav. and Loan Ass'n v. Guerra,* 479 U.S. 272, 281 (1987) (emphasis added and internal quotations omitted).

WLF fully supports Buckman's argument that Respondent's "fraud on the FDA" claim is impliedly preempted because it stands as an obstacle to the accomplishment of the full purposes and objectives of Congress. WLF will not repeat those arguments here but will instead focus on Buckman's other argument: that the "fraud on the FDA" claim is expressly preempted under 21 U.S.C. § 360k(a).

II. THE COURT OF APPEALS' NARROW CONSTRUCTION OF § 360k(a) IS NOT WARRANTED BY EITHER THE STATUTORY LANGUAGE OR THIS COURT'S DECISION IN *MEDTRONIC*

The MDA contains the following preemption provision:

> **(a) General rule.** Except as provided in subsection (b), no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement --
>
> (1) which is different from, or in addition to any requirement applicable under [the FDCA] to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a

> requirement applicable to the device under [the FDCA].
>
> **(b) Exempt Requirements.** Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a), under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if [certain conditions are met].

21 U.S.C. § 360k.

Purporting to follow *Medtronic*, the Third Circuit gave an extremely narrow reading to the preemption statute. By its terms, § 360k(a) is applicable only where: (1) there exists an applicable *federal* "requirement" of the type contemplated by § 360k(a)(1); (2) there exists a *State* "requirement" of the type contemplated by § 360k(a); and (3) the State "requirement" is "different from or in addition to" the applicable federal "requirement." Without even bothering to canvass the various candidates for an applicable federal "requirement," the appeals court dismissed out of hand Buckman's claim that § 360k(a) expressly preempted the "fraud on the FDA" claim:

> Based on [*Medtronic*], it is apparent that, within the meaning of § 360k, there is no federal "requirement" "applicable to the device" at issue here; nor is there a state "requirement" "with respect to" that device. Moreover, the state common law relied upon does not impose any obligation on Buckman inconsistent with federal law. As plaintiffs stress, 18 U.S.C. § 1001

> makes it a crime to make a fraudulent statement to a federal agency and 21 C.F.R. § 807.87(j) requires every pre-market notification to contain a statement that the information contained therein is believed to be truthful.

Pet. App. 13a.

The Third Circuit's analysis is unfaithful to the language of § 360k(a), to FDA's interpretation of that language, and to the holding of *Medtronic*. Even accepting fully every statement contained in *Medtronic* regarding the meaning of § 360k(a),[4] the Third Circuit misapplied each of the three principal elements of the preemption statute.[5]

A. There Exist Applicable Federal "Requirements" of the Type Contemplated by § 360k(a)(1)

The Third Circuit did not dispute that numerous federal anti-fraud requirements applied to Buckman's December 1985 § 510(k) submission to FDA or to any other § 510(k) submission. As set forth by the United States in its brief

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[4] WLF respectfully suggests, as argued more fully below, that while *Medtronic* was correctly decided on its facts, some of the Court's language was based on an incomplete understanding of FDA's interpretation and historical application of § 360k(a).

[5] Section 360k(a)(2) also requires that the State requirement "relate[] to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under [the FDCA]." The Third Circuit did not contend that Buckman had failed to demonstrate that this requirement had been met, however, and Respondent did not raise the issue in its opposition to the certiorari petition.

supporting the grant of Buckman's certiorari petition, those requirements included:

- 18 U.S.C. § 1001 (prohibiting false or fraudulent statements on any matter within the jurisdiction of a federal agency);

- 21 C.F.R. 807.87(h) (1985) (requiring, during the period relevant here, that parties making § 510(k) submissions must provide FDA with "[a]ny additional information regarding the device requested by the Commissioner that is necessary for the Commissioner to make a finding as to whether or not the device is substantially equivalent to a device in commercial distribution");

- 21 C.F.R. 807.87(k) (promulgated in 1992) (requiring each person submitting premarket notification to state that, "to the best of his or knowledge," all "data and information" are "truthful and accurate" and that "no material fact has been omitted").

U.S. Br. (June 7, 2000) at 12-13 n.5.[6]

The Third Circuit held, however, that those anti-fraud requirements were not federal "requirements" of the type contemplated by § 360k(a). Pet. App. 13a. It stated that that finding was compelled by *Medtronic*, which the appeals court interpreted as holding categorically that "[t]he § 510(k)

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[6] Federal law also imposes detailed requirements regarding the required contents of a § 510(k) submission. *See, e.g.*, 21 U.S.C. § 360(k), 360e(b); 21 C.F.R. §§ 807.87 - 807.93.

process thus established no federal requirement 'applicable to a device' within the meaning of the MDA." *Id.* at 12a.

Medtronic held no such thing. *Medtronic* considered a manufacturer's assertion that § 360k(a) preempted defective design, defective manufacture, and defective labeling claims with respect to its medical device, which was being marketed pursuant to § 510(k) approval. The Court did *not* indicate that *no* medical devices being marketed pursuant to § 510(k) approval were subject to federal "requirements" of the type contemplated by § 360k(a). Rather, the Court carefully considered each of the plaintiff's claims in turn. *Medtronic*, Part V, 518 U.S. at 492-502.

With respect to defective design claims, the Court held that none of the § 510(k) requirements relied on by the manufacturer imposed any sort of minimum design safety standards. *Id.* at 492-93. While those requirements ensured that § 510(k) devices were substantially equivalent to (and no more dangerous than) pre-1976 devices, they did not (the Court held) provide assurance that the § 510(k) devices were actually safely designed because there is no statutory mechanism designed to assure that all pre-1976 FDA devices are safely designed. *Id.*

With respect to defective manufacture and labeling claims, the Court held that the requirements relied on by the manufacturer were too general in nature to qualify as federal "requirements" under § 360k(a). *Id.* at 497-502. The Court explained:

> The generality of those [federal manufacturing and labeling requirements] make this quite unlike a case in which the Federal Government has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved *in a particular case* or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers. Rather, the federal requirements reflect important but entirely generic concerns about device regulation generally, not the sort of concerns regarding a specific device or field of device regulation that the statute or regulations were designed to protect from potentially contradictory state requirements.

Id. at 501 (emphasis added).[7]

Medtronic did not consider a "fraud on the FDA" claim of the type at issue here. Nonetheless, *Medtronic*'s rationale supports a finding that the anti-fraud requirements imposed on all § 510(k) applicants are federal "requirements" of the type contemplated by § 360k(a). Those requirements most definitely *are* intended to ensure nonfraudulent submissions -- unlike the design requirements at issue in *Medtronic*, which were intended to ensure equivalency, not design safety. Moreover, this is not a case in which FDA announced generally applicable requirements but never *specifically* applied them to the medical devices at issue (as was true of the manufacturing and labeling requirements at issue in *Medtronic*). Rather, FDA specifically examined Buckman's § 510(k) submissions and made a specific determination that the submission met FDA requirements (including FDA's anti-fraud requirements).

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[7] The Court was careful to add that it did "not believe that this statutory and regulatory language necessarily precludes 'general' federal requirements from ever pre-empting state requirements." *Id.* at 500.

Surely, that is the type of FDA application of federal requirements to specific devices that § 360k(a) was "designed to protect from potentially contradictory state requirements." *Medtronic*, 518 U.S. at 501.

B. There Exist State "Requirement[s]" of the Type Contemplated by § 360k(a)

The Third Circuit did not dispute that State common-law suits in general, and suits alleging fraud in particular, can result in requirements being imposed on medical device manufacturers subject to such suits. The court concluded, however, that *Medtronic* mandated the conclusion that such suits never qualify as State "requirement[s]" within the contemplation of § 360k(a):

> "These state requirements [imposed by State common law] therefore escape preemption not because the source of the duty is a judge-made common-law rule, but rather because their generality leaves them outside the category of requirements that § 360k envisioned to be `with respect to' specific devices such as pacemakers." [*Medtronic*, 518 U.S. at 502.] . . . Based on [*Medtronic*], it is apparent that, within the meaning of § 360k, there is no . . . state 'requirement' with respect to [the AcroMed] device.

Pet. App. 12a-13a.

The Third Circuit's conclusion that State common-law suits never qualify as State "requirements" within the meaning of § 360k(a) is a total misreading of *Medtronic*. To the contrary, five of the nine Justices stated explicitly that such suits would so qualify in a not-insignificant number of

cases. *Medtronic*, 518 U.S. at 510-11 (O'Connor, J., joined by Rehnquist, C.J., and Scalia and Thomas, JJ., concurring in part and dissenting in part); *id.* at 503 (Breyer, J., concurring in part and concurring in the judgment) ("[T]he MDA will sometimes pre-empt a state-law tort suit. I basically agree with Justice O'CONNOR's discussion of this point and her conclusion.") The Court did not reach its no-preemption finding because State common-law suits never amount to State "requirements" within the meaning of § 360k(a), but because they were "not the kinds of requirements that Congress and the FDA feared would impede the ability of federal regulators to implement and enforce specific federal requirements." *Id.* at 501.

Any doubt on that score was laid to rest by the Court's recent decision in *Geier v. American Honda Motor Co.*, 120 S. Ct. 1913 (2000). *Geier* held that State common- law suits challenging car makers' decisions not to install airbags in automobiles manufactured in the 1980s were impliedly preempted by the National Traffic and Motor Vehicle Safety Act of 1966 and regulations issued thereunder, even though such suits are merely a specific application of a generally applicable common-law duty not to sell defective products. *Id.* at 1928. Indeed, the Court on several occasions has invoked federal preemption statutes to find that State common-law suits do indeed impose "requirements" and thus are *expressly* preempted. *See, e.g., Cipollone*, 505 U.S. at 521, 522 (plurality); *id.* at 548-49 (Scalia, J., concurring in judgment in part and dissenting in part); *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 664 (1993).

In sum, the Third Circuit's holding that State common-law suits do not, because of their general applicability, constitute State "requirement[s]" within the meaning of

§ 360k(a) finds no support in any decision of this Court. To the contrary, there is simply no reason to distinguish between two State requirements having identical effects based solely on the method by which the requirements are imposed; to do so would have the "anomalous consequence[]" of "grant[ing] greater power (to set state standards 'different from, or in addition to,' federal standards) to a single state jury than to state officials acting through state administrative or legislative lawmaking processes." *Medtronic*, 518 U.S. at 504 (Breyer, J., concurring in part and concurring in the judgment). It is telling that Respondent, in its brief opposing certiorari, made no effort to defend this portion of the Third Circuit's decision.

C. The State "Requirement" Is "Different from or in Addition to" the Applicable Federal "Requirement"

The Third Circuit also relied on *Medtronic* to find that any State requirements imposed on Buckman by virtue of these lawsuits are not "different from, or in addition to" (within the meaning of § 360k(a)) any federal requirements imposed on Buckman in connection with the § 510(k) submission. The appeals court quoted *Medtronic*'s holding that:

> "Nothing in § 360k denies [a State] the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements. . . . The presence of a damages remedy does not amount to the additional or different 'requirement' that is necessary under the statute; it merely provides another reason for manufacturers to comply with identical existing 'requirements' under federal law."

Pet. App. 12a (quoting *Medtronic*, 518 U.S. at 495). From that holding, the Third Circuit derived its finding that § 360k(a)'s "different from, or in addition to" requirement had not been satisfied, stating:

> Moreover, the state common law relied upon does not impose any obligation on Buckman inconsistent with federal law. As plaintiffs stress, 18 U.S.C. § 1001 makes it a crime to make a fraudulent statement to a federal agency and 21 C.F.R. § 807.87(j) requires every premarket notification to contain a statement that the information contained therein is believed to be true.

Pet. App. 13a.

The Third Circuit's assertion that Respondent's suits are somehow consistent with FDA's approval of Buckman's § 510(k) submissions requires little refutation. In approving the § 510(k) submissions, FDA determined that the submissions complied with all federal regulatory requirements -- including the requirement prohibiting fraud on the agency. By filing a suit that challenges the propriety of the submissions, Respondent is also challenging the propriety of FDA's approval of those submissions. Of course, Respondent does not assert that FDA erred consciously; rather, Respondent alleges that FDA was hoodwinked by Buckman's fraud and would not have granted approval but for Buckman's deviousness. Respondent contends that it is only trying to impose, by means of State law, the very same result that FDA would have imposed had it not been the victim of fraud. But there is no avoiding the

reality that this suit seeks to impose a State "requirement" that is inconsistent with FDA's 1986 approval of the § 510(k) submissions, an approval that FDA has not seen fit to rescind despite repeated entreaties from Respondent.

As the United States recognizes:

> [T]he premise of respondent['s] state-law cause of action is that particular agency action should not and would not have been taken by a federal agency, and that damages should be awarded as if the conduct of [Buckman] that the FDA had *cleared* under the FDCA -- introducing the product onto the market -- was unlawful under the FDCA. A state court may not decline to give effect to an FDA decision that has not been rescinded by the FDA or set aside by a court. Cf. *Nantahala Power & Light Co. v. Thornburg*, 476 U.S. 953 (1986); *Chicago & North Western Transp. Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311 (1981). The federal government has a significant interest in the finality of its own administrative determinations, and under the Supremacy Clause those determinations should generally be questioned or set aside, if at all, only by the federal government itself.

U.S. Br. (June 7, 2000) at 16. It is inescapable that a State "requirement" that undermines the federal government's "significant interest" in the finality of its own administrative determinations must be deemed "different from, or in addition to" federal regulation of those subject to the federal administrative determinations.

III. PORTIONS OF *MEDTRONIC*'S DISCUSSION OF § 360k(a) WERE BASED ON AN INCOMPLETE UNDERSTANDING OF FDA'S INTERPRETATION AND HISTORICAL APPLICATION OF THE STATUTE

WLF has demonstrated above that the Third Circuit's decision is inconsistent with this Court's case law and that, when properly analyzed, *Medtronic* supports Buckman's contention that Respondent's claims are preempted by § 360k(a). WLF nonetheless respectfully suggests that the Court should use the occasion to re-examine some of the statements included within *Medtronic* in light of new evidence regarding FDA's interpretation and historical application of § 360k(a). WLF does not suggest that *Medtronic* was improperly decided, only that some statements in the decision are not historically accurate.

In attempting to discern the types of federal "requirements" that can give rise to § 360k(a) preemption, the Court in *Medtronic* substantially deferred to FDA regulations that attempt to give substance to the preemption provision. The Court explained that deference as follows:

> Congress has given the FDA a unique role in determining the scope of § 360k's pre-emptive effect. Unlike the statute construed in *Cipollone,* for instance, pre-emption under the MDA does not arise directly as a result of the enactment of the statute; rather, in most cases a state law will be pre-empted only to the extent that FDA has promulgated a relevant federal "requirement."

Medtronic, 518 U.S. at 495-96.

The Court heavily relied on one FDA regulation -- 21 C.F.R. § 808.1(d) -- in its analysis of the types of federal "requirements" that can give rise to preemption. That regulation provides, in pertinent part:

> State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements.

21 C.F.R. § 808.1(d). The Court picked up on FDA's use of the word "specific" (as in "specific counterpart regulations"), a word that does not appear in § 360k(a). *Medtronic*, 518 U.S. at 499-501; *id.* at 507 (Breyer, J., concurring in part and concurring in the judgment) ("[T]he regulation's word 'specific' does narrow the universe of federal requirements that the agency intends to displace at least some state law. Although the Court was unclear on this point, there is at least a suggestion from the Court that (based on the regulation's language) a federal "requirement" can not be deemed "specific," and thus can never have preemptive effect, unless the "requirement" applies to one specific medical device named therein or to a very small class of devices. *See, e.g., id.* at 500-01.

With all due respect, WLF believes that both the *Medtronic* plurality and Justice Breyer may have read too much into § 808.1(d) use of the word "specific." The historical record suggests that FDA used the word "specific" merely to indicate that a counterpart federal requirement

must be in existence before State requirements are preempted -- not in an effort to limit severely the universe of federal requirements that potentially could preempt state requirements. In other words, the relevant FDA statements in § 808.1(d) were aimed at ensuring that there would not be a regulatory vacuum immediately after the MDA was passed, in which all state requirements relating to medical devices would be preempted (even before FDA took any regulatory action pursuant to the MDA).

Section 808.1(d) was adopted in 1978. Both the 1977 Federal Register notice proposing federal regulations relating to § 360k(a) (42 Fed. Reg. 30383 (June 14, 1977)) and the 1978 Federal Register notice adopting those regulations in final form (43 Fed. Reg. 18661 (May 2, 1978) confirm that FDA did not intend the restrictive definition of "specific" ascribed to it by the *Medtronic*. Rather, those notices confirm that FDA used the word "specific" to express the agency's view that some counterpart federal requirement must be in existence before state requirements can be preempted by § 360k(a). For example, in its 1977 preamble to the proposed regulations, FDA explained:

> Consistent with his understanding of the intent of Congress, the Commissioner has narrowly construed the preemption provision so that [§ 360k(a)] . . . preempts State and local requirements only when *a particular Federal requirement becomes applicable to a particular device by operation of the act.* This avoids disruption of vital State and local programs relating to the regulation of medical devices and reduces the possibility of a regulatory hiatus that could result if State and local requirements were considered preempted prior to the time FDA implemented Federal

> requirements. The potential for such a regulatory void is real since it will require several years for FDA to implement fully its device regulatory programs.

42 Fed. Reg. at 30383 (emphasis added).

Statements made by FDA at the time its regulations became final in 1978 were to the same effect. For example, in rejecting arguments of commenters who argued that *all* State and local medical device requirements were preempted as of the date of the MDA's enactment in 1976, FDA explained:

> The Commissioner believes that both the language of [§ 360k(a)] and the legislative history of the [MDA] support the interpretation expressed in the proposal. . . Thus from a plain reading of [§ 360k(a)] . . . it is clear that the scope of preemption is limited to instances where there are *specific FDA requirements applicable to a particular device or class of devices*.

43 Fed. Reg. at 18662 (emphasis added).

As is apparent from context, the reference to "specific FDA requirements applicable to a particular device or class of devices" was not intended as a limitation on the type of federal requirements that would trigger preemption. By indicating that there must be "specific FDA requirements" in place before preemption occurs, the agency was saying nothing more than that some relevant federal requirement must actually be in place (not merely capable of being put in place) before counterpart state requirements are preempted.

In sum, WLF respectfully requests that the Court correct any confusion created by *Medtronic* and make clear that § 808.1(d)'s "specific counterpart regulations" language does not limit the universe of federal regulations capable of having preemptive effect to those regulations that reference by name a specific medical device or class of devices. Rather, the Court should explain that federal preemption is triggered so long as there are federal requirements in place that ensure that preemption does not lead to a regulatory vacuum. WLF notes that it a strong aversion to such regulatory vacuums that has caused the Court in the past to reject broad preemption arguments. *See, e.g., Medtronic,* 518 U.S. at 487 (plurality) ("Medtronic's construction of § 360k would therefore have the perverse effect of granting complete immunity from design defect liability to an entire industry that, in the judgment of Congress, needed more stringent regulation in order to provide for the safety and effectiveness of medical devices"). Because recognition of Buckman's preemption claim would leave in place powerful federal provisions designed to guard against fraud by medical device manufacturers, there is no danger that reversal of the decision below would create any sort of regulatory vacuum.

CONCLUSION

WLF respectfully requests that the Court reverse the decision of the U.S. Court of Appeals for the Third Circuit.

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IN THE

Supreme Court of the United States

THE BUCKMAN COMPANY,

Petitioner,

v.

PLAINTIFFS' LEGAL COMMITTEE,

Respondent.

On Writ of Certiorari To The United States Court Of Appeals For The Third Circuit

BRIEF OF MEDTRONIC SOFAMOR DANEK, INC. AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

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Other Authorities:

R.P. Davis, *Lack of Proper Automobile Registration or Operator's License as Evidence of Operator's Negligence,* 29 A.L.R. 2d 963 (1953 & Supp. 2000) 16

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INTEREST OF THE *AMICUS CURIAE*

Medtronic Sofamor Danek, Inc. ("MSD"), is successor in interest to Sofamor Danek Group, Inc. ("SDG"), parent of the largest suppliers of the spinal implants at issue in *In re Orthopedic Bone Screw Products Liability Litigation*, MDL 1014, from which this appeal arises.[1] SDG brought the initial motion to dismiss claims of fraud committed against the Food and Drug Administration ("FDA"), *see* MDL 1014 Docket No. ("MDL Dkt. #") 5103. The Court of Appeals held that SDG was not entitled to status as an appellant, *see* Appendix accompanying Petition for *Certiorari* ("Pet. App.") at 8a n.3, but SDG participated as *amicus curiae* in the Court of Appeals, *id.*, and in support of the petition for *certiorari* in this Court.

MSD should be permitted to participate as *amicus curiae* before this Court because its subsidiaries are suppliers of orthopædic bone screws, and thus are targets of the full range of "fraud on the FDA" claims in this litigation. Accordingly, MSD has relevant information concerning the broader impact of "fraud on the FDA" claims, both in this litigation and upon FDA administrative determinations generally.

MSD's participation as *amicus curiae* will assist the Court in understanding the profound impact of allowing common-law reexamination of the bases of FDA decisions — and by extension, of any federal administrative action — in private tort actions under state law.

SUMMARY OF ARGUMENT

Respondent Plaintiffs' Legal Committee ("PLC") represents hundreds of plaintiffs in personal injury litigation against suppliers of orthopædic bone screws used during plaintiffs' spinal fusion surgeries. "Fraud on the FDA" is one of the PLC's many state-law claims. The PLC asserts that virtually every important FDA decision concerning these screws since

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1. No counsel for any party authored any portion of this *amicus curiae* brief, and no one other than MSD made any monetary contribution to the preparation or submission of this brief. Supreme Court Rule 37.6.

1985 rests upon untrue information provided by the suppliers of these devices or their agents. This "fraud," the PLC claims, allows state-law juries to treat these FDA regulatory actions as if they did not exist, and to hold defendants liable for supplying products lacking any FDA marketing permission.

Without the Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. §§301, *et seq.*, there could be no claim that FDA was defrauded — because no FDA submission requirements would exist. Thus "fraud on the FDA" claims violate the FDCA's prohibition against private rights of action. 21 U.S.C. §337(a). Either under the express preemption provision of the Medical Device Amendments ("MDA") to the FDCA, 21 U.S.C. §360k(a), or under principles of implied preemption, claims of "fraud on the FDA" are preempted.

Without preemption, state-law juries could reexamine almost everything FDA does and could reach different conclusions regarding the validity of FDA actions. Refusal of state tort law to recognize an in-force federal administrative decision inherently conflicts with that federal decision and, more broadly, with the supremacy of federal law.

The pervasive interference with FDA actions that "fraud-on-the-FDA" claims entail is exemplified by the breadth of the PLC's charges against MSD here. The disruptive effect of such claims upon FDA administration of federal law is very real — as the course of this litigation likewise demonstrates.

ARGUMENT

In enacting the MDA in 1976, Congress sought to protect public health by balancing the need to regulate medical devices with the need for development of new and improved devices without excessive cost or delay.[2] A critical part of that

2. *See* S. Rep. No. 33, at 7 (1976) ("a balance [should] be struck between the need for continuing research and the need for improved patient protection"), at 13 (intent that "innovation is not stifled" and that " 'quack' devices or devices known to be unsafe or ineffective" not be allowed) (reprinted at 1976 U.S.C.C.A.N. 1074, 1075, 1076, 1083); H.R. Rep. No. 853, 94th Cong., 2d Sess. at 10 (1976) ("protection against unsafe, unproven,

balance — preservation of FDA's ability to do its job without being second-guessed in state tort litigation — is threatened by the claims before the Court on this appeal.

I. "Fraud On The FDA" Claims Expose FDA Decisions To Collateral Attack In State Courts, In Direct And Inherent Conflict With The Regulatory Scheme Enacted By Congress.

A. The PLC's Claims Seeking Nullification Of Almost Every FDA Decision Regulating Spinal Implants Between 1985 and 1998 Have Been Repeatedly Reviewed By FDA.

The PLC has brought "fraud on the FDA" claims against FDA decisions concerning every maker of orthopædic bone screws. *See* Pet. App. at 43a-44a; *In re Orthopedic Bone Screw Products Liability Litigation*, MDL 1014, 1996 WL 482977, at *2 (E.D. Pa. Aug. 22, 1996) (PTO 477). These claims controvert the validity of scores of FDA clearances of spinal implant devices since 1984, including FDA's 1995 decision to begin clearing "pedicle screws" as such and FDA's general reclassification of "pedicle screw spinal systems" proposed in 1995 and finalized in 1998. *See* 63 Fed. Reg. 40025 (FDA Jul. 27, 1998); 60 Fed. Reg. 51946 (FDA Oct. 4, 1995).[3] Repeatedly, the PLC has brought its extravagant charges to FDA's attention, but the Agency has rejected those claims, both explicitly and implicitly.

The *John Lee Ramey* complaint, the MDL Court's exemplar of claims against MSD's subsidiary, Danek Medical, Inc. ("Danek")[4] (reproduced in pertinent part as Appendix "A") reveals the ambitious scope of the PLC's "fraud on the FDA"

ineffective and experimental medical devices" is "counterbalanced by an equally strong conviction that excessive . . . regulation would stifle progress").

3. FDA's Final Rule was published on July 27, 1998, after oral argument in the court below. FDA decisions published in the Federal Register are entitled to judicial notice. 44 U.S.C. §1507.

4. *See In re Orthopedic Bone Screw Prods. Liab. Litig.*, MDL 1014, 1997 WL 186325, at *2 n.3 (E.D. Pa. Apr. 16, 1997) (PTO 861), *aff'd*, 193 F.3d 784 (3d Cir. 1999).

claims. It alleges that the initial 1986 FDA clearance of Danek "Luque II" components, used in surgery seven years later in 1993, was fraudulent because Danek supposedly misstated the "intended use"[5] of its screw components. App. "A" at 3a ¶¶90-100. There is no claim that Mr. Ramey, his surgeon, or anyone involved in his treatment knew of or acted in detrimental reliance upon any misstatement. *Id.* at 8a ¶¶126-28.

The *Ramey* complaint further alleges that Danek defrauded FDA with respect to devices not even used in Mr. Ramey's surgery. These allegations likewise involve "intended use," rather than the physical characteristics, medical risks, or medical benefits of any device:

- In 1988-89 and 1990-92, Danek allegedly misstated the "intended use" of various screw components of a device called the "TSRH" system. *Id.* at 6a-7a ¶¶105-15.
- In 1991-92, Danek allegedly misstated the "intended use" of the screw components of a device called the "Dyna-Lok" system. *Id.* at 7a-8a ¶¶120-25.

Other fraud allegations involve FDA's January 20, 1995 decision to clear TSRH screws labeled for use in the pedicles of the lumbar spine. Although this event occurred after Mr. Ramey's 1993 surgery, the *Ramey* complaint alleges that Danek (aided by other screw suppliers) submitted a false affidavit to FDA.[6] App. "A" at 13a-18a ¶¶244-75.

Still more fraud allegations in the *Ramey* complaint involve FDA's October 4, 1995 proposal to reclassify "pedicle screw spinal systems" to make future clearances easier to obtain. The PLC attacks a large "cohort study" that FDA concluded was "valid scientific evidence" of the safety and

5. "Intended use" is an FDA term of art. "Intended uses" described in a manufacturer's proposed labeling will be cleared only if FDA considers them substantially equivalent to intended uses of the predicate or preamendment device upon which the manufacturer's application for marketing and labeling clearance is based. *See* 21 C.F.R. §801.4.

6. All device clearances in the *Orthopedic Bone Screw* litigation involve the same "substantial equivalence" or "§510(k)" procedure discussed in *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 478-480 (1996).

effectiveness of bone screws when used for pedicle fixation. *Id.* at 9a-13a ¶¶240-43. *See* 60 Fed. Reg. at 51947, 51950-54.[7]

The PLC's "fraud on the FDA" allegations are not limited to one device, one supplier, or one incident. Each of hundreds of state-law cases attacks FDA decisions to allow marketing of most spinal fixation screws that now exist and to void regulatory steps FDA has taken since 1995 to address the administrative status of these devices. The PLC's "fraud on the FDA" claims are nothing less than an attempt to use state law to nullify over ten years of FDA regulatory activity. By these claims, the PLC seeks to have juries re-examine each of these FDA clearances, find them to be the product of fraud, and hold manufacturers liable as if no FDA clearance had ever been granted.

The history of the PLC's "fraud on the FDA" allegations demonstrates how second-guessing FDA decisions is the essence of such claims. FDA has examined the identical fraud allegations and found them wanting. FDA's proposal to reclassify spinal implants invited public comments, and the MDL Court allowed the PLC to use MDL discovery to make comments.[8] The PLC's public comments filed with FDA are 231 pages long and have 402 exhibits.[9] The PLC Comments asserted the same fraud charges made in this litigation against petitioner Buckman, AcroMed Corp. (which hired Buckman), Danek, and many others:

- "[D]evice manufacturers applied for §510(k) clearance to market the devices for pretextual uses." PLC Comments at 32; *see generally id.* at 33-37.

7. Reclassification is a separate process by which FDA can issue a lower device classification if presented with "valid scientific evidence" of a device's safety and effectiveness. 21 U.S.C. §360c(e); 21 C.F.R. §§860.7, 860.120-860.134.

8. *See* 60 Fed. Reg. at 51946 (calling for public comments); *In re Orthopedic Bone Screw Prods. Liab. Litig.*, MDL 1014, 1995 WL 764580, at *5 (E.D. Pa. Dec. 14, 1995) (PTO 179) (PLC may use confidential MDL documents in its public comments to FDA).

9. *See* "Comments by Plaintiffs' Legal Committee in *In re Orthopedic Bone Screw Products Liability Litigation*, MDL Docket 1014, Concerning Proposed Rule Making," FDA Dkt. No. 95N-0176 (filed March 1, 1996) ("PLC Comments").

- "[R]epresentations which AcroMed made to FDA concerning the intended use of its bone plates and bone screws were plainly false and misleading." *Id.* at 37; *see generally id.* at 34-39.
- The "1995 510k clearance . . . represents an unwarranted and unprecedented departure from the agency's prior position which violates the agency's own regulations and which occurred under suspicious circumstances." *Id.* at 215; *see generally id.* at 211-15.
- "[T]he Cohort Study . . . and, ultimately, the proposal of the downclassification regulation itself were the result of clandestine deals between certain employees of the FDA and industry." *Id.* at 90; *see generally id.* at 90-175.

In its July 27, 1998 Final Rule approving reclassification, FDA addressed the PLC's fraud claims. It refused to prohibit bone screws due to "deception":

> After reviewing all available data and information, . . . FDA does not believe that pedicle screw spinal systems present a substantial deception or an unreasonable and substantial risk of illness or injury. Consequently, FDA does not believe it would be appropriate to ban them.

63 Fed. Reg. at 40035-36 (Item 28). FDA further determined that prior screw clearances were not fraudulent or misleading and should be retained.[10] FDA reviewed the PLC's fraud allegations concerning the cohort study in great detail and rejected the PLC's claims point by point. *Id.* at 40029-30 (Items 2-3).

The PLC then filed a citizen's petition with FDA under 10 C.F.R. §10.30, seeking revocation of the January, 1995 TSRH §510(k) clearance, an investigation into supposed false, fraudulent or misleading Danek submissions, and/or a referral

10. *Id.* at 40030 (Item 3) (no corruption of data by financial relationships between surgeons and manufacturers); at 40031 (Item 8) (retaining prior Class II designation); 40032-33 (Items 13-16) (rejecting attack upon January, 1995 clearance and claims of corrupt "deal"); 40039 (Item 44) (retaining most prior labeling; allowing abbreviated resubmissions for devices previously cleared for pedicle use).

for criminal prosecution. MDL Dkt. #6732, Exhibit 1. The PLC's citizen petition rehashes the same "fraud on the FDA" claims:

- "Danek . . . and others agreed to obtain fraudulent and false documents and testimony . . . and submit such evidence to the FDA." *Id.* at 18.
- "Danek vigorously massaged the . . . affidavit to deliberately mislead the FDA." *Id.* at 23.
- "Based on the false, fraudulent or misleading information submitted by Danek . . . the FDA's determination of 'substantial equivalency' of the TSRH pedicle screw must be revoked." *Id.* at 25-26.

The PLC was again permitted to use confidential MDL discovery material in support of its citizen's petition.[11] FDA undertook another investigation of these allegations, but took no steps against Danek.[12]

In addition, hundreds of PLC plaintiffs filed complaints under the Federal Tort Claims Act ("FTCA"), 28 U.S.C. §§2671, *et. seq.*, alleging FDA negligence in granting the same clearances to market orthopædic bone screws. MDL Dkt. #6440, Exhibit F at ¶17 (exemplar complaint). The PLC's FTCA claims likewise claimed "fraud on the FDA" by reason of misstated "intended use." *Id.* at ¶¶14-17. The MDL court dismissed these FTCA claims. It found a "discretionary function" in order "to prevent judicial 'second-guessing' of legislative policymaking."[13]

Further, the PLC has a pending lawsuit against FDA under the Administrative Procedures Act, 5 U.S.C. §§551, *et. seq.* (1988) ("APA"). *See In re Orthopedic Bone Screw Prod-*

11. *In re Orthopedic Bone Screw Prods. Liab. Litig.*, MDL 1014 (E.D. Pa. Jul. 30, 1998) (PTO 1537); *In re Orthopedic Bone Screw Prods. Liab. Litig.*, MDL 1014 (E.D. Pa. May 21, 1998) (PTO 1448).

12. FDA's Status Report, filed in *Cosom, et al. v. United States Food & Drug Administration*, C.A. No. 98-4643, Dkt. #18 (E.D. Pa., filed Aug. 2, 1999) (related case docket to MDL 1014).

13. *In re Orthopedic Bone Screw Prods. Liab. Litig.*, MDL 1014, 1998 WL 964498, at *3 (E.D. Pa. Nov. 3, 1998). The PLC abandoned its appeal from that dismissal.

ucts Liability Litigation, MDL 1014, 1999 WL 455667 (E.D. Pa. Jul. 2, 1999) (PTO 1813) (PLC has standing to pursue APA claim). Once again, the PLC made its familiar attacks upon the cohort study and claimed that manufacturers "fraudulently sought and received FDA permission to market [bone screws] . . . for pretextual 'intended' uses." PLC APA complaint ¶¶69, 161-69.[14]

An additional measure of the PLC's effort to second-guess FDA is what it sought to put before this Court. **Everything** the PLC designated for the Joint Appendix (except complaints, declarations and judicial opinions) was in the exhibits to the PLC Comments submitted to FDA, and some **72 percent** of AcroMed/Buckman related exhibits submitted to FDA (54 of 75 AcroMed exhibits) were designated by the PLC here.[15]

Notwithstanding the numerous occasions upon which the PLC brought its "fraud on the FDA" allegations to FDA's attention — and FDA's access to all MDL discovery since January 5, 1996[16] — FDA first pursued and then finalized its October, 1995 proposal to reclassify the devices at issue in this litigation. 63 Fed. Reg. 40025 (FDA Jul. 27, 1998). Nor has FDA ever withdrawn or challenged the validity of any bone screw manufacturer's §510(k) clearances.

The PLC's "fraud on the FDA" allegations in the *Orthopedic Bone Screw* litigation, and FDA's adverse determination of them, expose the error of the lower court's reasoning. The PLC's attempt to overturn FDA clearances of every device in this litigation shows that its "fraud on the FDA" claims would impose a legal requirement — not to sell devices that FDA has cleared to be marketed — "different from or in addition

14. Amended Complaint, filed in *Cosom, et al. v. United States Food & Drug Administration*, C.A. No. 98-4643, Dkt. #5 (E.D. Pa., filed Dec. 7, 1998) (related case docket to MDL 1014).

15. The PLC's July 20, 2000 designation letter demanded that the Joint Appendix include Exhibits 1-37, 42-53, 65-67, 208 and 215 to the PLC Comments to FDA.

16. *In re Orthopedic Bone Screw Prods. Liab. Litig.*, MDL 1014, 1996 WL 901283 (E.D. Pa. Jan. 5, 1996) (PTO 192) (granting FDA access to MDL discovery).

to" FDA requirements under the FDCA. *See* 21 U.S.C. §360k(a). "Fraud on the FDA" claims are not just "different." They are incompatible with the FDA actions they attack, and are therefore preempted.

Just as starkly, these claims illuminate how "fraud on the FDA" claims inherently conflict with the same FDA actions they seek to nullify, and are thus impliedly preempted. *See Medtronic, Inc. v. Lohr,* 518 U.S. 470, 503 (1996) (recognizing conflict preemption under MDA) (plurality opinion), 507-08 (same) (Breyer, J. concurring); *McDermott v. Wisconsin,* 228 U.S. 115, 132-34 (1913) (applying conflict preemption under FDCA). Aside from the court below, every Court of Appeals presented with a state-law tort claim alleging fraud supposedly committed against a federal agency has found preemption because such claims "conflict" with, "second guess" or "collaterally attack" federal administrative determinations. *Lewis v. Brunswick Corp.*, 107 F.3d 1494, 1502 (11th Cir. 1997), *cert. dismissed,* 523 U.S. 1113 (1998); *Mitchell v. Collagen Corp.*, 126 F.3d 902, 914 (7th Cir.), *cert. denied*, 523 U.S. 1020 (1998); *Welchert v. American Cyanamid, Inc.*, 59 F.3d 69, 73 (8th Cir. 1995); *Reeves v. AcroMed Corp.*, 44 F.3d 300, 306-07 (5th Cir.) (identical claims), *cert. denied*, 515 U.S. 1104 (1995); *Papas v. Upjohn Co.*, 985 F.2d 516, 518-19 (11th Cir.), *cert. denied*, 510 U.S. 913 (1993). The course of this litigation — the PLC's repetitive attacks upon FDA's regulation of these products — establishes that the majority of courts are correct, and that the court below is mistaken.

"Fraud on the FDA" claims are preempted because they are inherently collateral state-law attacks upon in-force federal regulatory decisions. States, however, must accept supreme federal law. It is a "truism that States may not preempt federal law." *Adams Fruit Co. v. Barrett*, 494 U.S. 638, 649 (1990).[17] "Common law" may not be invoked to set aside federally issued approvals, arrived at after extensive review, because plaintiffs "disagree with the regulatory approach taken by the agency." *City of Milwaukee v. Illinois*, 451 U.S.

17. Superceded by statute as stated in *Deck v. Peter Romein's Sons*, 109 F.3d 383, 388 (7th Cir. 1997).

304, 323 (1981). Tort claims that "actually conflict[]" with federal law cannot stand. *Geier v. American Honda Motor Co.*, 120 S. Ct. 1913, 1922 (2000). The PLC may not, in these state-law cases, ask lay juries to reexamine and set aside FDA decisions that allow these medical devices to enter the nationwide market.

B. The Regulatory Structure Enacted By Congress Precludes The PLC's Attempted Collateral Attack Upon FDA Decisions.

The potential for state-law "fraud on the FDA" claims to disrupt FDA's administration of the FDCA is also apparent from the Agency's role in the statutory scheme. The FDCA does not invest FDA with authority to seek out and investigate drugs or medical devices for possible clearance. *Benton v. Kessler*, 799 F. Supp. 281, 284-85 (E.D.N.Y.), *mot. denied*, 506 U.S. 1084 (1992); *see* S. Rep. No. 468, at 204, 101st Cong., 2d Sess. (1990) (no FDA authority to establish clinical research facilities). Nor does FDA have authority to evaluate "off-label"[18] uses on its own volition. 21 U.S.C. §360c(i)(1)(E)(i-ii); S. Rep. No. 284, at 76, 104th Cong., 2d Sess. (1996). Like many administrative bodies, FDA acts in response to information that the governing statute requires regulated persons, and allows others, to submit to the Agency.

Requirements for submission of information to FDA are pervasive. The three avenues by which medical devices come onto the market each require evaluation of information submitted by manufacturers, distributors, and their agents.[19] So

18. Physicians may prescribe medical devices and drugs as they see fit, regardless of FDA-labeled indications. 21 U.S.C. §396. Such off-label use "is commonplace in modern medical practice and ubiquitous in certain specialties." *Washington Legal Foundation v. Henney*, 202 F.3d 331, 333 (D.C. Cir. 2000) (citations omitted). FDA has not regulated teaching of off-label uses, *id.* at 335; 65 Fed. Reg. 14286, 14287 (FDA Mar. 16, 2000), thus PLC attacks upon purported "promotion" of off-label use at medical seminars are without legal basis.

19. *See* 21 U.S.C. §360e(c); 21 C.F.R. §814.20 (describing information to be submitted to FDA in support of pre-market approval application); 21 U.S.C. §360c(e-f); 21 C.F.R. §860.123 (same; reclassification); 21 U.S.C. §§360(k), 360e(b); 21 C.F.R. §§807.87-807.93 (same; pre-market notification).

do approval processes for new drugs and biologics.[20] After FDA has given permission for a product to be marketed, manufacturers and distributors must provide a wide variety of additional information to FDA, any of which could lead to future FDA action.[21] Every action based upon submitted information is potentially subject to second-guessing and common-law nullification if "fraud on the FDA" claims survive preemption.

Nor does FDA need common-law assistance because it cannot defend itself from an onslaught of false information. Quite the contrary, the FDCA provides FDA with an imposing arsenal of sanctions should the Agency conclude that it has been the victim of fraud. In addition to felony criminal sanctions under 18 U.S.C. §1001, FDA has numerous administrative sanctions at its disposal:

- injunctions against violations or further marketing, 21 U.S.C. §332;

20. *See* 21 U.S.C. §355(a-d,i); 21 C.F.R. §§312.20-23, 314.50-54 (submission requirements for new drugs); 42 U.S.C. §262 (a,j); 21 C.F.R. §§601.3, 601.20-601.25 (submission requirements for new biologics).

21. **Devices:** *E.g.*, 21 U.S.C. §§360i (record keeping), 360j(f)(2) (variance from good marketing practices), 360l (post-market surveillance); 360ll, 360nn (a-b,d,f) (electronic inspection/reporting), 360aaa-3 (supplemental application for new use); 21 C.F.R. §§803.1-.56, 804.1-.35 (adverse experience), 806.10, 820.100 (corrections), 807.20-.31 (device/establishment listing), 810.10(d), 810.15-.16 (cease distribution/ recall), 820.30 (design/development), 820.70(b) (production/process changes), 820.120 (labeling), 820.181-.186, 821.50 (records), 820.198 (complaints), 821.20-.25 (device tracking), 860.7, 860.120-860.134 (reclassification). **Drugs:** *E.g.*, 21 U.S.C. §§355(k) (record keeping), 356b (postmarketing study), 356c (discontinuation), 360 (registration/listing), 360b(e)(1)(F) (failure to supplement application); 21 C.F.R. §§201.1-.15, 201.50-.57, 201.60-.63, 211.134(d,e), 314.70 (labeling), 207.20-.37 (establishment/drug listing), 211.180-.196 (record keeping), 211.198 (complaints), 310.303, 314.81, 314.420 (records/reports), 314.54 (indication changes), 314.70-.71 (supplement to approved application), 314.72 (change of ownership), 314.80 (adverse experience). **Biologics:** *E.g.*, 21 C.F.R. §§600.12 (record keeping), 600.14 (errors), 600.21-.22 (inspections), 600.80 (adverse experience), 600.81 (distribution), 601.4 (licenses), 601.12 (changes to approved applications), 601.26 (reclassification), 610.9, 610.11(c) (procedure modifications), 610.60-.64 (labeling).

- enhanced criminal penalties upon proof of "intent to defraud," *id.* §333(a);
- civil fines to $1,000,000, *id.* §§333(b)(2)(B), 333(f)(1)(A), 335b(a);
- seizure and forfeiture, *id.* §334(a)(2)(D);
- detention without prior notice, *id.* §334(g);
- barring implicated companies or individuals from involvement with further submissions to FDA, *id.* §335a(a-e);
- denial, suspension, or termination of activities tainted by fraud, *id.* §335a(f-h);
- withdrawal of approval, *id.* §335c;
- warning letters for "minor violation[s]," *id.* §336;
- permanent ban of the product at issue, *id.* §360f; and
- mandatory recall. *Id.* §360h(e).

Nor has FDA been reluctant to use its powers. Recent case law abounds with prosecutions of false statements to FDA.[22] Many FDA enforcement actions are for false or fraudulent submissions. For example, from March 1993 through January 2000, FDA permanently debarred 48 persons and temporarily debarred 2 others for providing false information.[23] FDA has also disqualified 87 clinical investigators from participation in clinical trials and has restricted numerous others.[24]

State-law "fraud on the FDA" claims thus are not needed to assist FDA enforcement efforts. Rather, such claims com-

22. *E.g., United States v. Sigma International, Inc.*, 196 F.3d 1314 (11th Cir. 1999); *United States v. Bhutani*, 175 F.3d 572 (7th Cir. 1999), *cert. denied*, 120 S. Ct. 1173 (2000); *United States v. Haas*, 171 F.3d 259 (5th Cir. 1999); *Takhar v. Kessler*, 76 F.3d 995 (9th Cir. 1996); *United States v. Ballistrea*, 101 F.3d 827 (2d Cir. 1996); *DiCola v. FDA*, 77 F.3d 504 (D.C. Cir. 1996); *United States v. Chatterji*, 46 F.3d 1336 (4th Cir. 1995).

23. *See FDA, Office of Regulatory Affairs, Office of Enforcement, Division of Compliance Policy — Debarment List* (last modified Jun. 20, 2000) <http://www.fda.gov/ora/compliance_ref/debar/default.htm>.

24. *See FDA Disqualified/Restricted Assurances List for Clinical Investigators* (last modified Jun. 13, 2000) <http://www.fda.gov/ora/compliance_ref/bimo/dis_ref_assur.htm>.

plicate FDA administration of the statute by pursuing matters FDA does not wish pursued. The FDCA gives complete prosecutorial discretion to FDA:

> Nothing in this chapter shall be construed as requiring the [FDA] to report for prosecution . . . minor violations of this chapter. . . .

21 U.S.C. §336. "The Act's enforcement provisions . . . commit complete discretion to [FDA] to decide how and when they should be exercised." *Heckler v. Chaney*, 470 U.S. 821, 835 (1985). As discussed, *supra*, at p. 6, FDA spent more than two years investigating the PLC's "fraud on the FDA" claims before rejecting them in issuing its 1998 Final Rule.

C. Allowing Tort Claims That Cannot Exist Apart From The FDCA Violates The Statute's Prohibition Of Private Rights Of Action.

In direct contrast to FDA's multi-faceted enforcement capabilities, the FDCA provides no enforcement role for would-be "private attorneys general" such as the PLC. The FDCA provides:

> Except as provided in subsection (b) of this section [relating to actions by state governments], all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States.

21 U.S.C. §337(a). Thus, this Court in *Medtronic*, 518 U.S. at 477 (plurality opinion), and every Court of Appeals to consider the question, have held that no private rights of action exist under the FDCA.[25] In §337(a), the FDCA "expressly restricts its enforcement to the federal government." *In re Orthopedic Bone Screw Products Liability Litigation*, 193 F.3d 784, 791 (3d Cir. 1999).

25. *E.g., Cottrell, Ltd. v. Biotrol International, Inc.*, 191 F.3d 1248, 1254-55 (10th Cir. 1999); *PDK Labs, Inc. v. Friedlander*, 103 F.3d 1105, 1113 (2d Cir. 1997); *Bailey v. Johnson*, 48 F.3d 965, 968 (6th Cir. 1995); *Mylan Laboratories, Inc. v. Matkari*, 7 F.3d 1130, 1139 (4th Cir. 1993), *cert. denied*, 510 U.S. 1197 (1994); *Rodriguez v. SK&F Co.*, 833 F.2d 8, 9 (1st Cir. 1987); *Fiedler v. Clark*, 714 F.2d 77, 79 (9th Cir. 1983); *Pacific Trading Co. v. Wilson & Co.*, 547 F.2d 367, 370 (7th Cir. 1976).

"Fraud on the FDA" claims are not ordinary product liability tort claims. They do not challenge any aspect of the product in question except its manufacturer's dealings with FDA. Without the FDCA and the submission procedures it mandates, there could be no claim for "fraud on the FDA." Attacks focused upon the regulatory pedigree of a medical device or drug correspond to no common-law tort. *Talley v. Danek Medical, Inc.*, 179 F.3d 154, 159-61 (4th Cir. 1999).

A supposed state-law claim incapable of existing apart from a federal statute is a *sub rosa* attempt to create a private right of action under the statute by operation of state law. This Court addressed the interplay of the FDCA and state law in a related context in *Merrell-Dow Pharmaceuticals Inc. v. Thompson*, 478 U.S. 804 (1986). In considering whether FDCA-related tort allegations gave rise to federal subject matter jurisdiction, the Court "assumed" (because neither party disputed) that Congress did not intend to allow private FDCA rights of action. 478 U.S. at 811. The Court noted that to allow FDCA violations as the sole basis for an ostensibly state-law cause of action conferring federal jurisdiction would "flout" this "assumed" Congressional intent:

> The significance of the necessary assumption that there is no federal private cause of action thus cannot be overstated. For the ultimate import of such a conclusion . . . is that it would flout congressional intent to provide a private federal remedy for the violation of the federal statute. We think that it would similarly flout, or at least undermine, congressional intent to conclude that the federal courts might nevertheless exercise federal-question jurisdiction and provide remedies for violations of [the FDCA] solely because the violation of the federal statute is said to be [an element of a claim] under state law. . . .

Id. at 812. State creation of extra-statutory FDCA "remedies" is equally suspect. "When we conclude that Congress has decided not to provide a particular federal remedy, we are not free to 'supplement' that decision in a way that makes it 'meaningless.' " *Id.* at 812 n.10 (citations omitted).

Congressional intent is at least as important to preemption as to determination of federal jurisdiction. "[T]he purpose of Congress is the ultimate touchstone of pre-emption analysis." *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992) (citation and quotation marks omitted). With *Medtronic*, the "assumption" in *Merrell Dow* of no private FDCA rights of action crystallized into an established legal rule. *See, supra*, at p. 13. Allowing "fraud on the FDA" claims to masquerade as "state law" thus "flout[s] congressional intent." *Merrell Dow*, 478 U.S. at 812. Therefore such claims are preempted.

Ad hoc reexamination of FDA decisions by lay juries in state-law actions around the country is contrary to the regulatory structure Congress intended. Even when FDA concludes it has been defrauded, the implicated approval is not void *ab initio*. FDA retains discretion to impose a lesser sanction than removing a product from the market. *United States v. Chatterji*, 46 F.3d 1336, 1341 (4th Cir. 1995). The PLC seeks to "use the threat of damages to require [defendants] to do exactly what [FDA] is empowered to excuse." *Chicago & North Western Transportation Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311, 326 (1981). The PLC wants state-law juries to disagree with FDA's 1998 rejection of the PLC's fraud allegations. The FDCA does not contemplate "a dual system of futile duplication of two authorities over the same subject matter." *California v. Federal Energy Regulatory Commission*, 495 U.S. 490, 502 (1990) (citation and quotation marks omitted). Preemption is necessary to preserve both FDA's exclusive enforcement powers and its prosecutorial discretion.

II. The *Medtronic* Decision Did Not Hold That "Fraud On The FDA" Claims Escape Preemption.

The court below did not purport to recognize a private FDCA action for "fraud on the FDA." Pet. App. at 13a. Rather, the court held, "[w]e see no inconsistency between the FDA having the exclusive prerogative of bringing actions to enforce the FDCA" and private plaintiffs "bring[ing] common-law fraudulent misrepresentation claims." *Id.* at 18a.

The error in this reasoning is that "fraud on the FDA" is fundamentally different than a traditional common-law fraud claim.

Traditional fraud is predicated upon a defendant, directly or indirectly, passing false information to a plaintiff, who detrimentally relies upon that information.[26] The PLC's complaints do not allege that any plaintiff, treating surgeon, or anyone outside FDA, knew of the allegedly false statements of "intended use" made to FDA, often many years before surgery.

Nor are tort actions based upon procedural irregularities. A "negligence *per se*" action will lie for violations of substantive safety standards.[27] Administrative guidelines, such as the content of administrative submissions, do not give rise to tort claims for their violation.[28] Procedural attacks upon federal administrative decisions are federal questions governed by the APA, *see, e.g.*, 5 U.S.C. §702; 28 U.S.C. §1331, and the PLC may continue to pursue that avenue. The truth of representations to FDA is for FDA to decide.

The court below also erred in employing a "presumption against preemption." Pet. App. at 18a. When Congress "legislate[s] . . . in a field which the States have traditionally occupied," there is a presumption against preemption. *Medtronic*,

26. *See* Restatement (Third) of Torts, Products Liability §9 & comment c (1997) (misrepresentation must be "in connection with the sale of a product"; reliance required); Restatement (Second) of Torts §402B & comment j (1965) (misrepresentation must be "to the public"; reliance required); Restatement (Second) of Torts §310 & comment c (1965) (misrepresentation must induce reliance, such as a third person's mistaken belief as to safety); Restatement (Second) of Torts §§537, 548 (1976) (must be reliance upon the misrepresentation).

27. *See* Restatement (Third) of Torts, Products Liability §4, comment a (1997) (violation claims limited to "final governmental edicts and directives . . . that establish binding safety standards").

28. *See* Restatement (Second) of Torts §288(a) (1965) (negligence *per se* not applicable to enactments that "protect the interests of the state or any subdivision of it as such"). Thus licensing statutes do not support negligence *per se*. *See Talley*, 179 F.3d at 161; R.P. Davis, *Lack of Proper Automobile Registration or Operator's License as Evidence of Operator's Negligence*, 29 A.L.R.2d 963 §5 (1953 & Supp. 2000) (collecting cases).

518 U.S. at 485 (plurality opinion). Such a presumption, however, "is not triggered when the State regulates in an area where there has been a history of significant federal presence." *United States v. Locke*, 120 S. Ct. 1135, 1147-48 (2000). There is hardly any area more remote from state-law concern than the policing of submissions to federal agencies by federally regulated persons. Any presumption here should favor preemption, since "one can assume that Congress or an agency ordinarily would not intend to permit a significant conflict." *Geier*, 120 S. Ct. at 1927.

The PLC's "fraud on the FDA" claims are dependent, not upon traditional tort reliance, but rather upon the claimed invalidity of FDA actions. The court below recognized this fact, but failed to appreciate its significance. *See* Pet. App. at 21a ("without Buckman's fraudulent representation, the FDA would not have given AcroMed a §510(k) clearance and that, absent a §510(k) clearance, AcroMed would not have access to the market"). Thus, the PLC's "fraud on the FDA" claims empower common-law juries to nullify administrative actions taken by FDA — by declaring the "absence" of those FDA actions.

The PLC does not request reconsideration of any FDA action regarding these devices upon a "truthful" record. Rather, the PLC wants juries to void FDA actions retroactively and to award damages. The conflict between this "tort" and a specific FDA requirement (here, clearance for marketing) imposed upon a specific device is total, because juries would be asked to treat standing FDA decisions as invalid. The conflict is also inherent, because unless the jury concludes that FDA decisions should be nullified, the PLC's claim cannot succeed. There was no such claim at issue in *Medtronic*.

Thus the court below should not have relied upon the rationale of the *Medtronic* plurality that the absence of private FDCA rights of action was "evidence of an intent *not* to preempt common law liability." Pet. App. at 15a (citing *Medtronic*, 518 U.S. at 487) (emphasis in original). The *Medtronic* plurality's observation was made in the context of rejection of an argument that §360k(a) preempted all state-law

claims. *Medtronic*, 518 U.S. at 487-89. That discussion is inapposite here, since the PLC has alleged numerous unpreempted claims such as design and warning defects. Nor did *Medtronic* involve any claim having nullification of an FDA action as an essential element. In construing a "splintered" decision like *Medtronic*, "the holding of the Court may be viewed as that position taken by those Members who concurred in the judgments on the narrowest grounds." *Marks v. United States*, 430 U.S. 188, 193 (1977). The court below ignored this stricture, since nothing in *Medtronic* addressed or implicated "fraud on the FDA" claims.

"Fraud on the FDA" is not analogous to any claim at issue in *Medtronic*, and the lower court's decision would avoid even preemption appropriate under *Medtronic*. No member of this Court disagreed with Justice Breyer that "a federal MDA regulation requir[ing] a 2-inch wire" would preempt a state tort claim "that use of a more than 1-inch wire is negligent." 518 U.S. at 504 (Breyer, J., concurring). But the court below would deny preemption of the same if it alleged that the "2-inch" regulation was the product of fraud upon FDA.

In particular, "fraud on the FDA" is the polar opposite of the "identity of requirements" claim that *Medtronic* unanimously held was not preempted.[29] *Medtronic* addressed only an undeveloped allegation that the defendant "violated FDA regulations." 518 U.S. at 495. The state-law duties in *Medtronic* thus could have "parallel[ed] federal requirements." *Id.* Here, "fraud on the FDA" would allow state-law juries to set aside what the PLC claims are fraudulently obtained FDA clearances – despite FDA's investigation of these allegations and the Agency's decision that they merited no action. A greater divergence between the requirements of federal and state law would be difficult to envision.[30]

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29. 518 U.S. at 494-97 (opinion of the Court), 513 (O'Connor, J. concurring, joined by the Chief Justice and Scalia and Thomas, JJ.)).

30. The PLC's assertion of "violations" of FDCA procedures cannot conceal that "fraud on the FDA" seeks to overturn the substantive FDA decisions resulting from those procedures. Courts are "not bound by the name, description or characterization" of state law, "but will determine for [themselves] the practical impact of the law." *Hughes v. Oklahoma*, 441 U.S. 322, 336 (1979) (citation and quotation marks omitted).

MSD is a national seller of medical devices, and the *Orthopedic Bone Screw* litigation is equally nationwide in scope. After the Court of Appeals' decision, however, MSD faces the likelihood that the validity *vel non* of the FDA clearances for its devices – and thus its ability to market those devices at all – may vary from state to state, or even within a state, depending on conflicting verdicts of lay juries.

Collateral attacks upon FDA decisions threaten suppliers of medical devices and drugs with liability, not for defective products, but for marketing their products in reliance upon FDA decisions that state law cannot retroactively annul. Because subjecting all FDA regulated manufacturers to inconsistent state-law decisions on the basic issue of whether they can legally market their products was not what Congress intended when it enacted the FDCA, this Court should reverse the decision below and hold that "fraud on the FDA" tort claims are preempted.

III. "Fraud On The FDA" Claims Disrupt FDA Administration Of Federal Law.

Where state law "presents the prospect of interference with the federal regulatory power," there is preemption as long as the potential disruption is more than "hypothetical." *Schneidewind v. ANR Pipeline Co.*, 485 U.S. 293, 310 (1988) (citation and quotation marks omitted). Preemption arises from "conflict of rules of law, of remedy, and of administration." *San Diego Building Trades Council v. Garmon*, 359 U.S. 236, 242 (1959). Where an administrative agency is involved:

> Congress did not merely lay down a substantive rule of law. . . . It went on to confide primary interpretation and application of its rules to a specific and specially constituted tribunal and prescribed [] particular procedure[s]. . . . Administration is more than a means of regulation; administration is regulation. We have been concerned with conflict in its broadest sense; conflict with a complex

and interrelated federal scheme of law, remedy, and administration.

Id. at 242-43 (citation and quotation marks omitted).

In its *amicus curiae* brief in support of *certiorari*, the United States pointed out that "fraud on the FDA" claims "could produce undesirable practical consequences" hindering FDA's ability to function. Brief for United States as *Amicus Curiae* [on Petition for *Certiorari*], at 16. Those adverse consequences are not hypothetical. They have occurred in this very litigation.

Excessive involvement of FDA personnel in private litigation is not a risk — it is a certainty — where "fraud on the FDA" is claimed. Here, given FDA restrictions upon availability of Agency personnel in litigation,[31] the litigants first competed to hire as their experts former FDA employees who had participated in the regulatory matters at suit.[32] In and of itself, the potential of lucrative employment opportunities for FDA employees with "fraud on the FDA" litigants should such claims survive preemption could well bias how future FDA internal deliberations are conducted or remembered.[33]

The PLC then turned its attention to FDA permanent and "special government employees"[34] engaged in FDA's

31. *See* 21 C.F.R. §20.1; *Giza v. Secretary of HEW*, 628 F.2d 748, 749 (1st Cir. 1980). *See generally United States ex rel. Touhy v. Ragen*, 340 U.S. 462 (1951) (administrative agencies may restrict litigants' access to agency personnel).

32. *See In re Orthopedic Bone Screw Prods. Liab. Litig.*, MDL 1014, 1995 WL 925673 (E.D. Pa. May 5, 1995) (PTO 45) (allowing PLC to use contested FDA witness).

33. For example, a former FDA employee hired by the PLC characterized an FDA meeting with Petitioner Buckman dramatically differently than did FDA itself in documents obtained through the Freedom of Information Act ("FOIA"). *Compare* FDA internal memorandum regarding Buckman meeting (Exhibit 2 to "Christiansen Declaration" accompanying MDL Dkt. #221), *with* Declaration of Carl Larson, Ph.D, P.E. ¶¶37-39 (Exhibit 8 to MDL Dkt. #4955).

34. "Special government employees" are, *inter alia*, officers or employees of the executive branch or an independent agency of the United States retained, designated or employed to perform, with or without compensation, for limited periods, temporary duties either on a full- or part-time basis. 18 U.S.C. §202. The FDA Commissioner may appoint members of the scientific and medical communities as special government employees. 21 C.F.R. §14.31(d-e).

ongoing reclassification of pedicle screw spinal systems, and particularly to FDA personnel involved with the cohort study of those devices that was the single largest piece of scientific evidence supporting reclassification.[35]

In July, 1995, the PLC noticed the depositions of twelve special and four permanent FDA employees — including all five members of FDA's advisory committee reviewing pedicle screw spinal systems.[36] The PLC's notice (reproduced as Appendix "B") demanded that these FDA employees testify and produce documents concerning 28 topics, ranging from FDA's internal deliberations to each employee's "compensation" and "daily activities" for more than two years. App. "B" at 22a-25a. The United States sought protective orders forbidding or limiting most of these the depositions, MDL Dkt. ##475, 536, and produced sworn evidence that exposing FDA special employees to hostile litigation discovery harms FDA's ability to recruit people with the necessary expertise. MDL Dkt. #475, Exhibit D ¶¶9-11; Exhibits F-H.

The MDL court denied the government's motions, and allowed the disputed discovery as to all but one FDA employee. *In re Orthopedic Bone Screw Products Liability Litigation*, MDL 1014, 1995 WL 925670 (E.D. Pa. Aug. 10, 1995) (PTO 87); *In re Orthopedic Bone Screw Products Liability Litigation*, MDL 1014, slip op. ¶2 (E.D. Pa. Aug. 21, 1995) (PTO 92). Thus, the "fraud on the FDA" claims in this very litigation resulted in multiple depositions of FDA personnel

35. The cohort study was a private medical study conducted "with input from FDA." 63 Fed. Reg. at 40030 (Item 2); *see id.* at 40026 n.1 (describing study generally).

36. The PLC's notice is Exhibit A to the United States' brief seeking a protective order. MDL Dkt. #475. The permanent FDA employees were: Melkerson, Yahiro, Mishra, and Wilkerson; and the special FDA employees were: Murray, Morrey, Mayor, Benson, Whitecloud, Kane, Crawford, Yuan, Rangaswamy, Carty, Greenwald and Hanley. *Id.* at Exhibit C ¶2. Of these, the members of the Advisory Committee were: Murray (chairman), Greenwald, Hanley, Carty, and Rangaswamy. MDL Dkt. #299, Exhibit 75, at pp.2-3.

— including an entire FDA-created deliberative body — over the policy-related objections of FDA.

The history of MDL 1014 also demonstrates the idiosyncratic ways that "fraud on the FDA" litigation can harm FDA's ability to carry out its regulatory mission. Here, FDA became so enmeshed in MDL 1014 that the litigation repeatedly impinged upon its administrative review of pedicle screw spinal systems.[37] But the worst effect of the *Orthopedic Bone Screw* litigation was that discovery relating to the alleged FDA fraud undermined and ultimately defeated FDA's ability to keep promises the Agency had made to the medical community.

To obtain frank responses from cohort study participants about surgical success and complications, FDA promised these surgeons anonymity. 63 Fed. Reg. at 40030 (Item 2). The PLC used litigation discovery to overcome FDA's promise. Within days of FDA's October 4, 1995 announcement of its decision to reclassify the devices at suit, the MDL court ordered a copy of FDA's entire cohort study file turned over to the PLC, allowing redaction of only the identities of participating surgeons and patients. *In re Orthopedic Bone Screw Products Liability Litigation*, MDL 1014, slip op ¶2 (E.D. Pa. Oct. 16, 1995) (PTO 147). The PLC then argued that the participants' names had to be released so it could file public comments with FDA opposing reclassification. MDL Dkt. #975. FDA sought to protect its promise of confidentiality, MDL Dkt. #1153, and temporarily succeeded in retaining the anonymity of most surgeons. *In re Orthopedic Bone Screw Products Liability Litiga-*

37. *See In re Orthopedic Bone Screw Prods. Liab. Litig.*, MDL 1014, slip op. at 1 (E.D. Pa. Jan. 2, 1996) (PTO 188) (FDA extends public comment period to accommodate MDL court); *In re Orthopedic Bone Screw Prods. Liab. Litig.*, MDL 1014, at Exhibit (E.D. Pa. May 28, 1996) (PTO 363) (FDA required to report to MDL court on audit of cohort study); *In re Orthopedic Bone Screw Prods. Liab. Litig.*, MDL 1014, 1996 WL 938334, at *1 (E.D. Pa. Jun. 6, 1996) (PTO 394) (FDA ordered to turn over confidential identities of cohort study participants to MDL court); *In re Orthopedic Bone Screw Prods. Liab. Litig.*, MDL 1014, 1999 WL 455667, at *7 (E.D. Pa. Jul. 1, 1999) (FDA ordered to report to MDL court in writing about its handling of PLC citizen petition). FDA also had to respond to multiple FOIA requests.

tion, MDL 1014, 1995 WL 764580, at *5 (E.D. Pa. Dec. 15, 1995) (PTO 179) (surgeon identities not disclosed except those who testified before the FDA advisory committee).

The PLC promptly penetrated the participating surgeons' anonymity by cross-referencing unredacted birth and surgery dates from FDA's file with dates and surgeon names supplied by the plaintiffs.[38] The MDL court permitted the PLC first to "break" FDA's code, *In re Orthopedic Bone Screw Products Liability Litigation*, MDL 1014, slip op. at 7-8 (E.D. Pa. Feb. 14, 1996) (PTO 254), and then to question participating surgeons in their depositions about submissions that FDA had promised would be kept anonymous and confidential.[39]

This litigation thus has damaged the medical community's confidence in FDA's ability to keep promises necessary to obtain physician cooperation with the Agency — something FDA "regrets." 63 Fed. Reg. at 40039 (Item 42).[40] As FDA has no power to conduct its own clinical studies, *see, supra*, at p. 10, the Agency needs to be able to enlist the medical community's help in future efforts to determine the safety and effectiveness of medical devices and drugs. The Agency's regu-

38. *See* MDL Dkt. #1184, at p.6 (PLC describes methodology), pp.18-24 (PLC chart indicating identification of 26 participating surgeons); MDL Dkt. #3720, at pp. 686-93 (same).

39. *See* "Decision and Recommendation No. 18 of Special Discovery Master (as to Deposition of Dr. Ensor Transfeldt)," MDL Dkt. #5636 (describing one example of PLC deposition about supposed "discrepancies" in surgeon's cohort study submissions). MSD does not know the total number of participating surgeons who lost FDA-promised confidentiality, but the MDL court ultimately ended discovery regarding the cohort study because of "the PLC's access to this data." *In re Orthopedic Bone Screw Prods. Liab. Litig.*, MDL 1014, 1998 WL 964495, at *2 (E.D. Pa. Nov. 3, 1998) (PTO 1601).

40. FDA also inadvertently disclosed participating surgeon identities to the PLC in discovery, although the PLC denies taking advantage. *See In re Orthopedic Bone Screw Prods. Liab. Litig.*, MDL 1014, slip op at 1-2 (E.D. Pa. Oct 26, 1995) (PTO 157) (ordering PLC not to use mistakenly produced FDA material); *In re Orthopedic Bone Screw Prods. Liab. Litig.*, MDL 1014 (E.D. Pa. Jan. 16, 1996) (PTO 193) (ordering return of material); *but see, In re Orthopedic Bone Screw Prods. Liab. Litig.*, MDL 1014, at Exhibit ¶7 (E.D. Pa. Jan. 4, 1996) (PTO 191) (PLC admits retaining digital copy of FDA's inadvertent production after returning hard copies).

latory efforts will be hindered if FDA cannot keep confidentiality promises to those whose help it needs — and if physicians who assist FDA in those efforts can be exposed to litigation such as this.

Legal recognition of "fraud on the FDA" would have other adverse practical ramifications. *First*, FDA regulations only require submission of one "intended use" to support device clearance. *See* 21 C.F.R. §807.92(a)(5). The PLC's FDA fraud claim effectively demands submission to FDA of every potential use known to an applicant — forcing FDA to wade through information it neither wants nor needs.

Second, suppliers of medical devices and drugs could not inform physicians of medical advances that utilize their products, as permitted by the FDCA, 21 U.S.C. §360aaa, without fear of exposing their FDA-recognized "intended uses" to state-law challenge as "fraudulent."

Third, because fraud, rather than a defective product, is the basis of the claim, "fraud on the FDA" could be asserted by competing device and drug companies to interfere with their competitors' products — thereby embroiling FDA not only in personal injury litigation, but also in the competitive machinations of regulated manufacturers. *Cf. Medtronic*, 518 U.S. at 494 & n.14 (discussing "procompetition" purpose of FDA clearance process at issue in this litigation).

CONCLUSION

Because "fraud on the FDA" claims seek state-law nullification of in-force FDA administrative actions, such claims necessarily seek to impose "differing" requirements under 21 U.S.C. §360k(a) and inherently conflict with and second-guess FDA decisions. For all of the above reasons this Court should reverse the United States Court of Appeals for the Third Circuit and hold that "fraud on the FDA" claims are both expressly and impliedly preempted by federal law.

Respectfully submitted,

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Dated: September 13, 2000

**Member of the Supreme Court Bar*

APPENDICES

APPENDIX A

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

John Lee Ramey and Candice Ramey,
Plainfiffs,

v.

Danek Medical, Inc.; Sofamor-Danek Group, Inc.; Warsaw Orthopedic, Inc.; Eduardo Luque; Charles E. Johnston, II; Richard Ashman, Ph.D.; Gary Lowery; George Rapp; Ensor Transfeldt; John A. Herring; Thomas Whitecloud, III; Thomas A. Zdeblick; Youngwood Medical Specialties, Inc., f/k/a/ National Medical Specialty, Inc., f/k/a/ Stuart Medical Specialty, Inc.; Stuart Medical, Inc., f/k/a/ Stuart Drug and Surgical Supply, Inc.; Texas Scottish Rite Hospital for Crippled Children; American Academy of Orthopaedic Surgeons; North American Spine Society; Scoliosis Research Society; Spinal Science Advancement Foundation; Acromed Corporation, Charter No. 614043; Acromed Corp. (Now Acromed Corporation, Charter No. 614043); Acromed Corporation, Charter No. 816942; Acromed, Inc., Charter No. 811415; Acromed Incorporated (Now Acromed Inc., Charter No. 811415); Acromed Incorporated, Charter No. 816943; Acromed Holding Corporation, Charter No. 811416; Acromed Corporation (Now Acromed Holding Corporation, Charter No. 811416); Ace Medical Company; Advanced Spine Fixation Systems, Inc.; Cross Medical Products, Inc.; DePuy-Motech, Inc.; Smith & Nephew Richards, Inc.; Sofamor, S.N.C.; Sofamor, Inc.; Synthes (U. S.A.); Synthes, Inc.; Synthes North America, Inc.; Synthes; A.G.; Zimmer, Inc.,
Defendants.

MDL 1014 CIV. NO. 96-422

D. MD. CIV. NO. 95 CV 3194

JURY TRIAL DEMANDED

FIRST AMENDED COMPLAINT

* * *

3. On March 1, 1993, Dr. A.H. Dudley performed surgery on Plaintiff at Children's Hospital in Baltimore, Maryland and implanted a Danek pedicle screw fixation device known as the Luque device in Plaintiffs spine.

* * *

Count I: Fraud (on the FDA)

84. Plaintiff repeats and realleges each and every allegation set forth in the paragraphs above and further alleges the following.

85. The claims made in Count I of this Complaint are made against Danek and Sofamor-Danek.

86. The Luque II plate and screw device was developed by Eduardo Luque ("Luque") specifically for use in spinal surgery involving the lower back. The device consists of plates and screws which are intended to be attached to the lumbar spine with screws inserted posteriorly through the lumbar pedicles in order to provide a means of internal stabilization in connection with spinal fusion surgery.

87. On March 26, 1986, Warsaw Orthopedic submitted a 510(k) notification to the FDA for the Luque II device which was described as the "Interpeduncular Segmental Fixation System."

88. Less than two months later, on May 6, 1986, the FDA determined that the device was a Class III device which was not substantially equivalent to any pre-enactment device and which, therefore, could not be sold in the United States without a premarket approval based data developed in prospective clinical trials pursuant to an approved IDE. In explaining this decision, the agency stated that the decision was based on the fact that there had not been adequate demonstration that there was a pre-amendment device with a design substantially equivalent to The Luque System and on the fact that it posed potential risks not exhibited by other spinal fixation systems, such as:

"1. greater chance of neurological deficit due to imprecise screw placement or the event of screw failure;

2. pedicle fracture during placement of the screw;

3. soft tissue damage or inadequate fusion due to bending or fracture of device components; and

4. greater risk of pseudoarthrosis due to instability of design."

89. Determined to immediately sell the Luque II device for spinal fixation, Danek conceived and implemented an unlawful and deceptive scheme to bring the Luque II device to market without premarket approval and without the development of the kind of safety and efficacy data necessary to obtain such premarket approval.

90. The unlawful plan contemplated that:

(a) Danek would fraudulently seek 510(k) clearance of the components of the Luque II system as "bone plates" and "bone screws" for use in repairing fractures of the long bones even though the sole intended use of the Luque II system was in spinal applications;

(b) Once clearance from the FDA was obtained, Danek would contend that the FDA determination of substantial equivalence constituted official notification from the FDA that the devices were safe and effective and that such devices could be introduced for commercial use; and

(c) Consistent with Danek's goal to sell the Luque II device in interstate commerce for its intended use as a pedicle screw fixation device, Danek would promote the device by using physicians such as Luque to train other physicians in spinal applications of the Luque II device.

91. Using this approach, on June 5, 1986 Danek submitted a 510(k) notification for the same device components which made up the ISF system for which 510(k) clearance had previously been denied.

92. In the June 5, 1986 submission, the system components were described as "the Warsaw Orthopedic Bone Plate and Cancellous Bone Screw."

93. The notification claimed that "[t]he screws are designed for use in all fractures treated with two or more cancellous lag screws, such as intracapsular fractures of the hip and femoral condyle and tibia plateau fractures."

94. With respect to the plate components, the notification stated that "[s]pecific application is of course within the purview of the physician, but the use of the device in conditions such as long bone osteotomy, pelvic fracture and arthrodesis of the knee and/or ankle is obvious."

95. Subsequent correspondence with the FDA on behalf of Danek in connection with the notification emphasized that the device was intended for general orthopedic use in the long bones and not for pedicle fixation.

96. A July 2, 1986 letter written on behalf of Danek to the FDA in connection with the notification falsely stated that the Warsaw screws were "intended for use in the treatment and management of orthopedic injuries or conditions that in the view of the physician will benefit from the application of metallic screws or metallic plates and screws. Generally, this means for the repair of osseous fractures or conditions using screws having enhanced holding power in the cancellous bone."

97. Further misrepresentations appear in an August 1, 1986 letter written on behalf of Danek to the FDA regarding use of the cancellous bone screws, in which it was stated that "[t]he manufacturer intends that the screw will be used to treat fractures of cancellous bone."

98. In reasonable and justifiable reliance on the misrepresentations made regarding the intended use of the plates and screws which were the subject of the June 5, 1986 510(k) notifications, the FDA cleared these components as substantially equivalent to pre-amendment devices.

99. The representations made by Danek in obtaining these 510(k) clearances were intentionally false and

misleading. L.D. Beard, who at the time was the President and Chief Executive Officer of Danek, conceded at a deposition that the intended use of the bone plates and bone screws which were the subject of the June 5, 1986 510(k) notifications was not for repair of fractures of the long or flat bones as set forth in those 510(k) notifications. Rather, he admitted that the sole intended use of the system and system components was for use in spinal applications (i.e., pedicle screw fixation) and that the only reason why the FDA was told otherwise was so that clearance could be obtained so that the device could enter the market where Danek intended to promote and sell it only as a pedicle screw/spinal plate fixation system.

100. At the time the FDA made its substantial equivalence determination with regard to the Luque II device (which was presented to the FDA as "Warsaw Orthopedic Bone Plates and Cancellous Bone Screws"), it was ignorant of the fact that Danek had misrepresented the intended use of the Luque II Plates and Screws and that the sole intended use of the device components was as pedicle screws and spinal plates assembled as a spinal fixation system.

101. On June 27, 1986, an application was submitted for Danek to conduct clinical trials of the Luque Intrapeduncular Segmental Fixation System pursuant to the Investigational Device Exemption provisions of the Food, Drug and Cosmetic Act. The stated purpose of the IDE application was to develop data on the safety and effectiveness of the Luque II device for pedicular fixation.

102. The FDA granted approval to conduct the IDE trials involving a limited number of physicians and institutions.

103. However, the Luque II IDE failed to generate sufficient information on safety and efficacy to permit the FDA to grant premarket approval of the device for its intended use as a pedicle screw fixation device.

104. Nevertheless, Danek marketed and promoted the Luque II device on a massive basis outside of the IDE trial solely for its intended use as a pedicle screw fixation device.

105. Danek also manufactures, markets, distributes and sells the Texas Scottish Rite Hospital ("TSRH") spinal system. This instrumentation system was developed by Richard Ashman, Ph.D., ("Ashman"), John Herring, M.D. ("Herring") and Charles Johnston, M.D. ("Johnston") at the Texas Scottish Rite Hospital in Dallas, Texas.

106. The TSRH system employs a pair of rods arranged along the vertical axis of the spine which are connected to the vertebrae with hooks, screws or both.

107. Danek did not seek clearance from the FDA to market the screw components of the TSRH system for use in the pedicles of the lumbar vertebrae which, anatomically, lie above the bony base of the spine known as the sacrum.

108. However, it did seek 510(k) clearance for sacral application of the TSRH screws.

109. On September 2, 1988 a 510(k) notification was submitted to the FDA for what was described as TSRH "sacral screws."

110. Based on the representation that these screws were intended to be used in the sacrum, the FDA determined, on April 6, 1989, that the TSRH sacral screws were substantially equivalent to pre-enactment device components.

111. On September 12, 1990, Danek submitted a 510(k) notification to the FDA for the TSRH Variable Angle Sacral Screw.

112. The notification stated that the Variable Angle Sacral Screw was a modification of the TSRH sacral screw and followed the same intended use.

113. Based on the representation that these screws were to be used in the sacrum, the FDA determined on January 22, 1992 that TSRH Variable Angle Sacral Screw was substantially equivalent to a pre-amendment device.

114. The representations made in the 510(k) notifications to the FDA concerning the intended use of TSRH sacral and variable angle sacral screws were intentionally false and misleading.

115. At the time Danek submitted these 510(k) notifications, Danek intended that the screws which were labeled as "sacral screws" would be used by surgeons in the pedicles of the lumbar spine. Indeed, Danek funded a book which was authored by the developers of the system concerning its use. The book was specifically written to go along with the system as part of the system itself. It was to serve as a "cornerstone" for courses and workshops concerning the use of the system and "as a way to stimulate users' interest in purchasing and employing the instrumentation." One Chapter of this book, Chapter 5, is dedicated exclusively to a discussion involving the use of TSRH "sacral screws" in the pedicles of the lumbar spine in order to create a fixation construct for treatment of degenerative spinal instability. The text and illustrations in this regard are unmistakable. Chapters 4, 6 & 7 of the book also describe the use of TSRH screws in the lumbar pedicles. These chapters together account for over half of the book.

116. Consistent with this, Danek expressly viewed the TSRH system as a "pedicle screw fixation system."

117. Danek did request and receive approval to conduct IDE clinical trials involving 10 institutions and 240 subjects in order to obtain clinical data on the safety and efficacy of pedicle screw fixation with the TSRH system.

118. The TSRH pedicle screw IDE did not develop sufficient data to result in a successful application for premarket approval.

119. Nevertheless, Danek marketed and promoted the TSRH device on a massive basis outside of its IDE trial for its intended use as a pedicle screw fixation device.

120. Danek also manufactures, distributes and sells the so-called "Dyna-Lok" Spinal Fixation System. The system is a plate and screw device.

121. On September 7, 1991 Danek submitted at [sic] 510(k) notification for the Dyna-Lok Fixation System. The application falsely stated that the device was substantially equivalent to the Warsaw Bone Plate, now called the Danek

Plate, and that the bone screws used in the Dyna-Lok device were substantially equivalent to the TSRH Sacral Screw.

122. In reliance on Danek's representations concerning the intended use of the Dyna-Lok device, on December 17, 1992, the FDA determined that the device was substantially equivalent to pre-amendment devices.

123. Danek's 510(k) notification for the Dyna-Lok Fixation System misrepresented the intended use of the device. The device was designed and intended exclusively for use as a pedicle screw fixation device.

124. All of the misrepresentations made by Danek to the FDA as set forth in Count I of this Complaint were made intentionally to deceive the FDA and to induce it to issue 510(k) clearances for the Luque II, TSRH, and Dyna-Lok devices and device components in order to provide Danek with a pretext to claim that the devices could be lawfully introduced into interstate commerce.

125. The FDA was ignorant of the fact that these devices and device components were intended by Danek for use as pedicle screw fixation devices.

126. Were it not for these fraudulent acts and statements, the FDA would not have issued 510(k) clearances for Danek's pedicle screw fixation devices and device components for any purposes, the devices would not have been introduced into interstate commerce, and the Plaintiff would not have been exposed to the dangerous device which was surgically implanted in the Plaintiff.

127. The FDA, Plaintiff and Plaintiffs' implanting physicians relied upon Danek to make truthful statements to the FDA in its 510(k) notifications regarding the intended use of the devices at issue so that Plaintiff would not be implanted with a dangerous medical device that was never proven to be safe and effective for the use for which it was intended, i.e., pedicle screw fixation.

128. As a direct and proximate result of Danek's misrepresentations as set forth in Count I of this Complaint, Plaintiff suffered severe and permanent physical harm

including injuries to his spine, spinal nerves, spinal nerve roots and surrounding tissues, cells, nerves and vascular structures. As a result, Plaintiff has in the past and will in the future suffer a loss of earnings, an impairment in earning capacity, physical pain, mental anguish, emotional distress, permanent disability, liabilities for medical and rehabilitative expenses and other forms of damage, loss and harm.

* * *

B. The Intercompany/Association Conspiracy

* * *

238. By 1992, the manufacturers and sellers who marketed pedicle screw fixation devices in violation of federal law and the physicians and professional associations they conspired and acted in concert with expressed a need to find a means to avoid criminal prosecution and civil liability in connection with their past unlawful promotion of pedicle screw fixation devices and to legitimize the sale of such devices in the future.

239. In furtherance of the original goals of the intercompany/association conspiracy and as a means to avoid liability for past wrongful acts, those who participated in the intercompany/association conspiracy adopted and implemented a two-part scheme.

240. First, all of the members of the intercompany/association conspiracy agreed to the creation, funding, and support of a trade association which was named the Spinal Implant Manufacturers Group ("SIMG"), and a "Scientific Committee" to conduct a "Cohort Study" of pedicle screw fixation in a fraudulent and misleading manner and to use the "results" of this deceptive and misleading study:

(a) to achieve reclassification of pedicle screw fixation devices so that they could be legally marketed without the successful completion of prospective clinical trials and/or premarket approval;

(b) to avoid criminal prosecution for illegal sales and distribution of pedicle screw fixation devices; and

(c) to provide "scientific" evidence for use as part of a defense to litigation in which patients claimed that they suffered harm as a result of the use of pedicle screw fixation devices.

241. Pursuant to this scheme, data regarding the outcome of patients treated for spinal fracture and degenerative spondylolisthesis was gathered by SIMG, the Scientific Committee, AAOS, AANS, SRS, and NASS from spine surgeons who were selected to participate in the study; the data were received and analyzed by Biometric Research Institute, Inc. ("BRI"); and the results of the study were reported to an FDA advisory panel on July 22, 1994 and in a special issue of *Spine* magazine which was published on October 15, 1994.

242. Pursuant to the plan adopted by the members of the intercompany/association conspiracy, the manner in which the Cohort Study was conducted and reported was intentionally deceptive and materially misleading in that, among other things:

(a) In reporting the results of the study, it was claimed that the study represented an "independent" analysis of the safety and efficacy of pedicle screw fixation. However, the professional societies which designated representatives to serve on the Scientific Committee which was responsible for conducting the study (AANS, AAOS, SRS, and NASS), had significant financial relationships with the manufacturers and sellers of the pedicle fixation devices that were the subject of the Cohort Study which were not disclosed when the results of the study were reported;

(b) In reporting the results of the study, it was claimed that the study represented an "independent" analysis of the safety and efficacy of pedicle screw fixation. However, each of the members of the Scientific Committee which claimed responsibility for conducting the Cohort Study had a significant financial relationship with manufacturers of pedicle screw fixation devices, which became substantially

more generous on completion of the study. This circumstance was concealed from those to whom the study was reported.

(c) In reporting the results of the study, it was claimed that the study represented an "independent" analysis of the safety and efficacy of pedicle screw fixation. However, Hansen Yuan, M.D., who was chairman of the Scientific Committee which claimed responsibility for conducting the study was negotiating with two major pedicle screw manufacturers to license a new pedicle screw fixation device while the study was proceeding. Those manufacturers had made offers to pay him as much as one million dollars in cash and a percentage royalty worth as much as twenty-five million dollars for the license, making it explicit that the amount which Dr. Yuan would realize under these proposed arrangements was directly dependent on whether the FDA reclassified pedicle screw fixation devices as a result of the Cohort Study. Dr. Yuan concealed these transactions when the results of the Cohort Study were reported. Moreover, when Dr. Yuan was questioned concerning these transactions at a deposition and at a hearing, he falsely stated that he did not engage in these negotiations until the Cohort Study had been completed and gave false and misleading information concerning the agreement which he ultimately entered into for the licensing of the pedicle screw fixation system.

(d) In presenting the results of the Cohort Study to the FDA's advisory panel, the Scientific Committee represented that a sample of the Cohort study data was "assessed by an independent auditor pursuant to a plan which was based on a blinded, random site selection process" which demonstrated that the submitted data were accurate when, in fact, the only "audit" which was done was a revisit of five sites by a masters-level employee of Dr. Yuan, who later

admitted significant inaccuracies in data reporting and other material failures to comply with the study protocol.

(e) SIMG and the Scientific Committee adopted and implemented a policy to destroy virtually all documents related to the Cohort Study before the study was reported to the FDA advisory panel in violation of an existing document preservation order entered by a federal court and with the intent to destroy evidence concerning the manner in which the Cohort Study was created and implemented;

(f) BRI, which received and analyzed the Cohort Study data was directed by Order of the United States District Court for the Eastern District of Pennsylvania to produce all computer diskettes and documents in its possession concerning the study. Not only did BRI fail to comply with that order but it also falsely stated, under oath, that the computer diskettes in its possession concerning the study had technical defects which prevented it from making usable copies, that its computer backup system containing Cohort Study data had mysteriously "crashed," destroying the information encoded therein, and that it had virtually no documents in its possession concerning this study. After a lengthy hearing, however, it was "discovered" that BRI had usable computer diskettes which could be copied, that there was no "crash" of the BRI computer backup system and that BRI had boxes full of documents which were properly subject to production;

(g) In presenting the results of the Cohort Study, it was represented that the Cohort Study was "conducted" by the Scientific Committee and that the study data was collected or analyzed by the Scientific Committee when, in fact, the Scientific Committee was not familiar with the manner in which the study data was processed, the way in which it was verified, or the procedures which were developed and applied with regard

to missing, incomplete, and inconsistent data and did not perform or understand the statistical treatment of the Cohort Study data;

(h) The Cohort Study was purportedly designed to demonstrate the difference between the outcome of patients treated with pedicle screw fixation and the outcome of patients who were treated for the same conditions by other methods. However, the study intentionally distorted that comparison by excluding data from physicians who infrequently used pedicle screw fixation and frequently used other methods to treat the conditions under consideration;

(i) The physicians who participated in the study inaccurately reported the post-operative conditions of patients who underwent pedicle screw fixation surgery, selectively excluded data for patients who should have been included in this study and selectively included the data from patients who should have been excluded from the study;

(j) The study exacerbated the potential for reporting and selection bias by providing that data be submitted anonymously by spine surgeons; and

(k) In reporting the results of the study the fusion outcome in patients who received pedicle screw fixation surgery was falsely inflated in relation to the fusion rate achieved in patients who underwent fusion surgery without pedicle screw fixation.

243. To this date, Defendants involved in the Danek and intercompany/association conspiracies are attempting to use this fraudulent and misleading Cohort Study as a means of escaping liability in this and related litigation.

244. Beginning in the Spring of 1993, as the second aspect of the effort to achieve the legal marketing status for pedicle screw fixation devices through fraudulent and deceptive means, Danek and other manufacturers and sellers of pedicle screw fixation devices engaged in a collaborative industry-physician effort to deceive the FDA with respect to

the commercial use of a Harrington lag screw for pedicle fixation prior to 1976 in order to persuade the FDA that pedicle screws were substantially equivalent to pre-enactment devices and therefore deserving of 510(k) clearance without analysis of safety or efficacy.

245. Specifically, in furtherance of the goals of the intercompany/association conspiracy, AcroMed, Danek, Sofamor and Zimmer agreed to obtain fraudulent and false documents and testimony purporting to prove that Zimmer had made and sold a commercially available pedicle screw in the United States prior to May 28, 1976 and submit such documents and testimony to the FDA to secure 510(k) approval for the Danek TSRH system.

246. AcroMed, Danek, Sofamor and Zimmer knew that the position of the FDA was that Zimmer had not made and sold a pedicle screw in the United States prior to May 28, 1976 that would meet the pre-requisites of 510(k) clearance.

247. In fact, Zimmer's Director of Regulatory Affairs knew as early as November 1987 that the position of the FDA was that Zimmer had not made and sold a pedicle screw in the United States prior to May 28, 1976 that would meet the pre-requisites of 510(k) clearance.

248. Zimmer knew on or before May 20, 1992 that other manufacturers were "pursuing reclassification to pre-enactment status based upon some old Zimmer drawings found in a surgeon's files."

249. Rick Treharne of Danek called Michael Mayock of Sofamor, who was a former Zimmer employee, and requested that Mayock prepare an affidavit to be submitted with the Danek TSRH 510(k) application claiming falsely that Mayock had personal knowledge of a pre-enactment sale in the United States of a Zimmer pedicle screw.

250. Treharne and Mayock drafted numerous revisions of a proposed affidavit until Treharne composed and sent Mayock a document described by Treharne as the "perfect affidavit," which Mayock executed.

251. Mayock obtained approval from Sofamor before executing this "perfect" affidavit and another affidavit and then transmitted the same to Sofamor.

252. Mayock claimed in his affidavit that Zimmer made a pedicle screw product prior to May 28, 1976 that would meet the prerequisites of 510(k) approval, asserting falsely that Zimmer shipped a pedicle screw made by Zimmer in the United States to Zimmer distributor Keith Bartow, who then sold the screw to a Mexican doctor named Luque.

253. Keith Bartow did not sell pedicle screws made by Zimmer in the United States to Dr. Luque prior to May 28, 1976.

254. In fact, Keith Bartow did not even meet Dr. Luque until the early 1980's.

255. Danek Chief Executive Officer Beard called Zimmer President Ron Davis and requested that Zimmer perform research of pre-1976 pedicle screw usage to assist in Danek's TSRH 510(k) application.

256. Zimmer President Ron Davis instructed Zimmer General Counsel Timothy Wendt to conduct such research of pre-1976 pedicle screw usage to assist in Danek's TSRH 510(k) application.

257. AcroMed Director of Regulatory Affairs Christianson also called Zimmer General Counsel Timothy Wendt and requested that Zimmer perform research of pre-1976 pedicle screw usage to assist in Danek's TSRH 510(k) application.

258. In addition, Danek employee Bailey Lipscomb or Danek employee Rick Treharne called Zimmer's Director of Regulatory Affairs Max Sherman and requested that Zimmer conduct research of pre-1976 pedicle screw usage to assist in Danek's TSRH 510(k) application.

259. Sherman has testified that Zimmer had a policy against giving assistance to other manufacturers by providing them with supporting documents for 510(k) applications.

260. Nevertheless, Wendt ordered Zimmer employees to perform research of pre-1976 pedicle screw usage to assist in Danek's TSRH 510(k) application.

261. Zimmer did not charge Danek for its research of pre-1976 pedicle screw usage to assist in Danek's TSRH 510(k) application.

262. For pre-amendment status, FDA Compliance Policy Guide 7124.19 requires the following: (1) at least one United States sale pre-May 28, 1976 of a product made in the United States; (2) catalogue advertising; and (3) no research support. To prove the first point, the FDA requires either invoices or an affidavit explaining their absence.

263. Wendt executed two affidavits to be submitted to the FDA to assist in Danek's TSRH 510(k) application, explaining the absence of invoices purportedly proving at least one United States sale of a Zimmer pedicle screw pre-May 28, 1976.

264. Zimmer employee Gary Tanner prepared an affidavit to be executed by former Zimmer employee Ralph Welling that repeatedly used the term "pedicle screw" in reference to purported pre-May 28, 1976 screw usage by Zimmer, even though Welling had never before used the term "pedicle screw" or even heard such term before seeing his proposed affidavit.

265. Tanner prepared an affidavit to be executed by Ralph Welling that referenced purported pre-May 28, 1976 "pedicle screws" shipments and usage even though Welling had no personal knowledge whatsoever regarding whether or not the referenced screws were actually manufactured, sold or used.

266. The affidavits by Mayock, Wendt and Welling were essential to convince the FDA to approve the Danek TSRH 510(k) on the basis that they purportedly established that there was a United States pre-May 28, 1976 sale of a Zimmer "pedicle screw."

267. AcroMed, Danek, Zimmer and Sofamor knew that the factual claim in the Danek TSRH 510(k) filing that Zimmer made and sold a commercial pedicle screw in the United States that was not involved in research prior to May 1976 was false.

268. Indeed, Zimmer filed a "Supplemental Motion For Summary Judgment On The Plaintiffs' Conspiracy Claims And Zimmer, Inc.'s Brief In Support Of Supplemental Motion For Summary Judgment On The Plaintiffs' Conspiracy Claims" (hereinafter "Supplemental MSJ") on or about March 15, 1996 in MDL 1014, providing in pertinent part that:

(a) "Zimmer has never marketed any device which includes a screw intended for use in the lumbar pedicles" (p. 5);

(b) "Zimmer has never marketed a pedicle screw fixation system for use in the United States" (p. 10);

(c) "Zimmer does not now and has never marketed a spinal device which includes a screw intended for use in the lumbar pedicles of the spine" (p. 11);

(d) "Zimmer did not even have a product in the pedicle screw market" (p. 16);

(e) "The undisputed fact is that Zimmer did not have a product to sell in that market [pedicle screws]" (p. 17);

(f) "Zimmer never marketed a device that included a screw intended for use in the lumbar pedicles" (p. 18); and

(g) "Zimmer does not market a pedicle screw device" (p. 25).

269. Neither AcroMed, Danek, Sofamor nor Zimmer advised the FDA, and the FDA did not know, that Zimmer asserted that it "never marketed a pedicle screw fixation system for use in the United States," in direct conflict with the position set forth in the Danek TSRH 510(k) application.

270. Danek's Lipscomb and AcroMed's Christianson flew to Kansas together and collaborated on additional research for the Danek TSRH 510(k) application.

271. Sofamor employee Mayock testified that the joint research effort by AcroMed, Danek, Sofamor and Zimmer was "like a loose confederation."

272. Zimmer's Max Sherman stated in a July 14, 1989 memorandum that 510(k) approval for portions of Zimmer's

spinal implant system "would be a good defense item for litigation. (It would indicate Zimmer developed PSI using proper approval procedures.)"

273. AcroMed stated in a May 15, 1995 News Release (TMI 00686) that its first 510(k) clearance would "seriously undercut those allegations" by Plaintiffs "in the pending products liability litigation against AcroMed."

274. In 1995, Danek submitted a 510(k) notification requesting clearance to market pedicle screws for use in its TSRH system. The claim of substantial equivalence to a pedicle screw device in commercial distribution prior to 1976, which was necessarily required to obtain 510(k) clearance, was based primarily on the Mayock and Wendt affidavits, the former of which was overtly false, and the other, materially misleading.

275. Based on and in reliance on the representations and affidavits contained in Danek's 510(k) submission, on January 20, 1995, the FDA announced its determination that it had cleared pedicle screws pursuant to the Danek 510(k) premarket notification for limited indications. Subsequent clearances were granted to other manufacturers including AcroMed, SNR and Cross based on the Danek clearance.

* * *

APPENDIX B

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: ORTHOPEDIC BONE SCREW PRODUCTS LIABILITY LITIGATION	:	MDL DOCKET NO. 1014
THIS DOCUMENT RELATES TO ALL ACTIONS	:	

NOTICE OF DEPOSITIONS

PLEASE TAKE NOTICE that plaintiffs in the above-entitled action will take the depositions, upon oral examination, of the following persons on the dates, at the times and in the places listed. The depositions are being taken pursuant to Paragraph 2 of Pretrial Order No. 51. At each deposition, each witness shall be required to produce those documents listed in Schedule "A" to this Notice. The depositions shall take place before a Notary Public and shall be stenographically transcribed and may also be recorded by videotape.

Name of Deponent	Date and Time of Deposition	Place of Deposition
David A. Murray	Monday, July 31, 1995 - 9:30 A.M.	Sheraton University Hotel and Conference Center 801 University Avenue Syracuse, NY
Paula Wilkerson	Monday, July 31, 1995 - 9:30 A.M.	Silver, Freedman & Taff 1100 New York Ave., NW Suite 700 Washington, DC 20005
Bernard F. Morrey	Tuesday, August 1, 1995 - 9:30 A.M.	Raddison Plaza Hotel 150 S. Broadway Rochester, MN 55904
Michael B. Mayor	Tuesday, August 1, 1995 - 9:30 A.M.	Hanover Inn Main & Wheelock Streets Hanover, NH 03755
Daniel R. Benson	Wednesday, August 2, 1995 - 9:30 A.M.	Red Lion Hotel 2001 Point West Way Sacramento, CA

Name of Deponent	Date and Time of Deposition	Place of Deposition
Thomas Whitecloud	Wednesday, August 2, 1995 - 9:30 A.M.	Cummings, Cummings & Dudenhefer 416 Gravier Alison House New Orleans, LA 70130
Mark Melkerson	Thursday, August 3, 1995 - 9:30 A.M.	Silver, Freedman & Taff 1100 New York Ave., NW Suite 700 Washington, DC 20005
William J. Kane	Thursday, August 3, 1995 - 9:30 A.M.	Hines, Mili & Olson 700 North Star East 608 Second Avenue South Minneapolis, MN 55402
Nirmal Mishra	Friday, August 4, 1995 - 9:30 A.M.	Silver, Freedman & Taff 1100 New York Ave., NW Suite 700 Washington, DC 20005
Curtis Dickman	Friday, August 5, 1995 - 9:30 A.M.	Fountain Suites 2577 West Greenway Rd. Phoenix, AZ
Martin Yahiro	Monday, August 7, 1995 - 9:30 A.M.	Silver, Freedman & Taff 1100 New York Ave., NW Suite 700 Washington, DC 20005
Alvin Crawford	Monday, August 7, 1995 - 9:30 A.M.	Waite, Schneider, Bayless and Chesley Co., L.P.A. 1513 Central Trust Tower Cincinnati, OH 45202
Hansen Yuan	Tuesday, August 8, 1995 - 9:30 A.M.	Sheraton University Hotel and Conference Center 801 University Avenue Syracuse, NY
Steven Mardjetko	Tuesday, August 8, 1995 - 9:30 A.M.	Much, Shelist, Freed, Denenberg & Amend 200 North LaSalle Street Suite 2100 Chicago, IL 60601
Thomas Zdeblick	Wednesday, August 9, 1995 - 9:30 A.M.	Edgewater Hotel 666 Wisconsin Avenue Madison, WI
Leela Rangaswany	Wednesday, August 9, 1995 - 9:30 A.M.	Conway, Crowley & Hugo 4 Fameuil Hall Marketplace Boston, MA 02109

Name of Deponent	Date and Time of Deposition	Place of Deposition
Steven Garfin	Thursday, August 10, 1995 - 9:30 A.M.	Tschirn & Thomson 7825 Fay Avenue Suite 340 LaJolla, CA 92037
Claudia Thomas Cartie	Tuesday, August 10, 1995 - 9:30 A.M.	Latham Hotel 612 Cathedral Street Baltimore, MD
Seth Greenwald	Friday, August 11, 1995 - 9:30 A.M.	Weisman, Goldberg & Weisman 1600 Midland Building Cleveland, OH 44115
Edward N. Hanley	Friday, August 11, 1995 - 9:30 A.M.	Hyatt Charlotte 5501 Carnegie Blvd. Charlotte, NC 28202
Christine Incorvaia	Monday, August 14, 1995 - 9:30 A.M.	Silver, Freedman & Taff 1100 New York Ave., NW Suite 700 Washington, DC 20005
Philip Molgren	Monday, August 14, 1995 - 9:20 A.M.	Much, Shelist, Freed, Denenberg & Amend 200 N. LaSalle Street Suite 2100 Chicago, IL 60601

Martis Ann Brachtl, Esquire
Stanley Chesley, Esquire
John J. Cummings, III, Esquire
Calvin Fayard, Jr., Esquire
Wendell Gauthier, Esquire
Will Kemp, Esquire
Arnold Levin, Esquire
Joseph L. Messa, Esquire
Darryl J. Tschirn, Esquire

By_____
Arnold Levin
Liaison Counsel

PLAINTIFFS' LEGAL COMMITTEE

SCHEDULE "A"

I. DEFINITIONS

As used herein, the following terms have the following meanings:

1. The term "document" is used in its broadest possible sense to refer to any document or other tangible matter or thing which may be properly subject to a request under the Freedom of Information Act and your implementing regulations.

2. The term "Cohort Study" refers to the historical Cohort Study of Pedicle Screw Fixation in Thoracic, Lumbar and Sacral Spine Fusions, the results of which were reported to the Orthopedic and Rehabilitation Devices Advisory Committee Panel meeting on July 22, 1994 and in the October, 1994 supplement to *Spine* magazine.

3. The term "relevant premarket notifications" refers to all premarket notifications submitted under Section 510k of the Food, Drug and Cosmetic Act at any time from January 1, 1993 through the present in which the intended use of the device was posterior attachment to the spine by means of screws inserted through the spinal pedicles.

II. DOCUMENTS REQUESTED

1. All documents reflecting, relating or referring, directly or indirectly, to the Cohort Study.

2. All documents reflecting, relating or referring to each and every event involved in planning for the Cohort Study, including any plans or protocols which were abandoned or not otherwise carried out.

3. All documents reflecting, relating or referring to the implementation of any plans for the Cohort Study including transactions undertaken and ultimately not included within the study.

4. All documents reflecting, relating or referring to any results of the Cohort Study including, without limitation, results which were not reported as part of the study.

5. All documents reflecting, relating or referring to any communications among any persons including physicians, organizations of physicians, manufacturers, organizations of manufacturers, the Food and Drug Administration, the National Institute of Health, and any other person, entity or organization with regard to the Cohort Study.

6. All documents reflecting, relating or referring, directly or indirectly, to the payment of money or any item of value to or for the benefit of any person in connection with the Cohort Study.

7. All documents reflecting, relating or referring, directly or indirectly, to clinical data solicited in connection with the Cohort Study.

8. All documents reflecting, relating or referring, directly or indirectly, to the analysis, review, audit, retention and/or destruction of any clinical data solicited or received in connection with the Cohort Study.

9. All documents reflecting, relating or referring to the identity of each and every person who was involved in any aspect of the Cohort Study.

10. All documents reflecting, relating or referring to any audit procedure which was proposed or implemented in connection with the Cohort Study.

11. All documents reflecting, relating or referring to any analysis, summary or meta-analysis of literature with regard to the subject of pedicle screw fixation which was used or proposed to be used in connection with the Cohort Study including analyses used for purposes of selecting study "controls," and meta-analyses and summaries presented or proposed to be presented to the July 22, 1994 Advisory Panel meeting.

12. All documents reflecting, relating or referring to the identity of each physician who submitted data in connection with the Cohort Study.

13. All documents reflecting, relating or referring to any transaction in which any FDA employee or consultant and/or any physician and/or entity who supplied data in connection with the Cohort Study received or had a relative or entity with which he was affiliated receive money, securities, items of value or the promise of money, securities or other items of

value, contingent or otherwise, from any member of the Spinal Implant Manufacturers Group.

14. All documents reflecting, relating or referring, directly or indirectly, to directions, instructions, protocols, procedures, or the like in connection with the Cohort Study.

15. All data derived from the Cohort Study in the form of computer tapes, disks, diskettes, hard drive, or other electronic storage media together with such documents as are necessary for the complete understanding of the manner in which such data have been stored and may be effectively retrieved.

16. All documents reflecting, relating or referring to each and every "control" used in connection with the Cohort Study.

17. All documents reflecting, relating or referring to the payment of money, the conveyance of anything of value or the promise of such payment or conveyance, contingent or otherwise, by any person to or for the benefit of any FDA consultant or any employee of the FDA in connection with the Cohort Study.

18. All documents reflecting, relating or referring to any communications between any employee of the FDA and/or any FDA consultant, on the one hand, and any member of the Spinal Implant Manufacturers Group, Advanced Biosearch Associates, North American Spine Society, Sciolosis Research Society and/or the American Association of Orthopedic Surgeons, on the other had, with respect to the subject of pedicle screw fixation and/or the regulation thereof.

19. Each of the relevant premarket notifications.

20. All documents reflecting, relating or referring to the FDA's consideration of each of the relevant premarket notifications.

21. All documents reflecting, relating or referring to any communications regarding each of the relevant premarket notifications and any agency action thereon.

22. All documents reflecting, relating or referring to each "predicate device" for which substantial equivalence was claimed in each of the relevant premarket notifications.

23. All documents reflecting, relating or referring to any communications between any employee of the FDA and/or any FDA consultant on the one hand, and any member of the

Spinal Implant Manufacturers Group, Advanced Biosearch Associates, North American Spine Society, Sciolosis Research Society and/or the American Association of Orthopedic Surgeons, on the other hand, with respect to each of the relevant premarket notifications.

24. All documents reflecting, relating or referring to the payment of money or the conveyance of any thing of value to or for the benefit of any FDA employee or consultant in connection with any of the relevant premarket notifications and any agency action thereon.

25. All documents which reflect any agency action on each of the relevant premarket notifications.

26. All documents reflecting, relating or referring to the justification for any agency action taken in response to each of the relevant premarket notifications including any agency determination to "clear" a device for use in the human pedicles.

27. All calendars, log books, telephone logs, or other documents reflecting the daily activities and conduct of each deponent to whom this Notice of Deposition and Subpoena Duces Tecum is addressed during the period from January 1, 1993 through the present.

28. All documents reflecting any FDA analysis of data with respect to spinal fixation devices which was generated pursuant to Investigational Device Exemptions granted to Acromed, Inc., Buckman & Company, Sofamor, S.N.C., Stuart, Smith & Nephew Richards, Inc., Zimmer, Advanced Spine Fixation System, Inc., and/or Cross Medical Products.

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No. 98-1768

In the Supreme Court of the United States

THE BUCKMAN COMPANY,

Petitioner,

v.

PLAINTIFFS' LEGAL COMMITTEE,

Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Third Circuit

BRIEF *AMICUS CURIAE* OF THE MEDICAL DEVICE MANUFACTURERS ASSOCIATION IN SUPPORT OF PETITIONER

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QUESTION PRESENTED

Whether federal law preempts state-law tort claims alleging fraud on the Food and Drug Administration during the regulatory process for marketing clearance applicable to certain medical devices.

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INTEREST OF *AMICUS CURIAE*

The Medical Device Manufacturers Association ("MDMA") is a national trade association based in Washington, D.C. that represents nearly 130 independent manufacturers of medical devices, diagnostic products and health care information systems. MDMA seeks to improve the quality of patient care by encouraging the development of new medical technology and fostering the availability of beneficial innovative products. To achieve these goals, MDMA represents its members' collective interests before the United States Congress, the Food and Drug Administration ("FDA"), other federal agencies, and courts that develop, implement or interpret policies that affect the medical device industry. MDMA has a significant interest in this case because it raises important liability issues with broad implications for the entire medical device industry.[1]

SUMMARY OF ARGUMENT

The Medical Device Amendments of 1976 expressly and impliedly preempt the state law fraud claims asserted by Plaintiffs. The claims are expressly preempted under 21 U.S.C. § 360k(a), because they would establish state law

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[1] Pursuant to Supreme Court Rule 37.6, *amicus curiae* affirms that no counsel for either party authored this brief in whole or in part, and no person or entity other than *amicus curiae* and its members made a monetary contribution to the preparation or submission of the brief.

Pursuant to Supreme Court Rule 37.2, written consent to the filing of this brief has been obtained from counsel for both parties, and the documents reflecting consent have been filed with the Clerk's office.

requirements "different from, or in addition to," applicable federal requirements. The relevant federal requirements require parties seeking premarket clearance to submit information to the FDA to demonstrate that the device under review is substantially equivalent to a predicate device that was in commercial distribution before the Medical Device Amendments were enacted. This information includes the device's proposed labeling describing its "intended use."

"Intended use" is a term of art that refers to the functional capabilities of the device, or in the words of the FDA, "what the device does." The purpose of the federal submission requirement is solely to allow the FDA to determine whether the device's functional capabilities as described in the proposed labeling are the same as those set forth in the labeling of the predicate device. Significantly, the description of "intended use" is *not* a representation of the manufacturer's subjective intent about what the *actual* uses of the device by medical professionals may be following clearance. It is well settled that once the FDA has cleared a medical device for one use, medical professionals may legally employ the device for other, "off-label," uses. The required statement of "intended use" says nothing about the submitter's subjective intent with respect to such off-label uses.

Plaintiffs' claims would establish state law disclosure requirements that are different from, and in addition to, these federal submission requirements. If plaintiffs' claims were allowed to proceed, they would require parties that seek premarket clearance to disclose their subjective intent with regard to possible off-label uses once clearance is obtained. Because federal law imposes no such requirement, Plaintiffs' claims are preempted under section 360k(a).

The Court also should hold that Plaintiffs' claims are impliedly preempted, because they would frustrate the

Congressional purpose underlying the Medical Device Amendments. If such claims were not barred by preemption, they would interfere with the FDA's statutory responsibility to make critical new medical devices available promptly for patient treatment. Such claims certainly would entangle agency personnel in tort litigation between private parties. Involving FDA officials in such tort litigation would divert them from their important product clearance functions, thereby delaying the availability of critical medical devices.

Fraud on the agency claims also would create incentives to burden the FDA with additional submissions of information. If fraud on the agency claims were preserved from preemption, manufacturers would attempt to protect themselves against fraud liability by submitting to the agency all information that is even arguably relevant to product clearance, to guard against later allegations that it made material omissions in communications with the agency. The resulting burden on the agency to review the information submitted would further delay product clearances, thereby undermining the congressional purpose.

Preserving fraud on the agency claims also would interfere with the FDA's authority to remedy fraud in its premarket clearance processes. The FDA has extensive authority to remedy such fraud, and the proper role of a private party is to refer alleged frauds for investigation by the agency, not to pursue independent remedies for fraud under state law. The Supremacy Clause does not allow private parties to invoke state law to meddle with this federal scheme, and as a result Plaintiffs' claims are impliedly preempted.

ARGUMENT

The state law claims at issue in this case assert that Petitioner, The Buckman Company, is liable for fraudulently misrepresenting the intended use of orthopedic bone screws in premarket clearance notifications that it filed with the FDA on behalf of AcroMed Corporation. Perhaps because Buckman is not itself a medical device manufacturer, and instead is a regulatory consultant with no control over its clients' manufacturing operations, the claims do not allege that there were any product defects in the bone screws. The claims instead assert simply that the bone screws never would have been on the market but for the alleged misrepresentations in the premarket clearance notifications. Through these claims, Plaintiffs seek to second-guess the FDA's actions under federal law in reviewing AcroMed's notifications and clearing the bone screws for marketing.

The Supremacy Clause does not permit Plaintiffs to invoke state law to meddle in this manner with the federal regulatory scheme. Plaintiffs' claims should be dismissed, because Congress has both expressly and impliedly preempted them.

I. THE MEDICAL DEVICE AMENDMENTS EXPRESSLY PREEMPT PLAINTIFFS' STATE LAW CLAIMS FOR FRAUD ON THE FDA

A. The Medical Device Amendments Expressly Preempt Fraud Claims That Would Impose State Law Requirements Different From, or in Addition to, Federal Requirements

Congress's intent to preempt state law "may be 'explicitly stated in the [federal] statute's language or implicitly contained in its structure and purpose.' " *Cipollone v. Liggett Group*, 505 U.S. 504, 516 (1992) (quoting *Jones v. Rath*

Packing Co., 430 U.S. 519, 525 (1977)). The Medical Device Amendments of 1976 ("MDA") contain the following express preemption provision, which Congress intended to be a "general prohibition on non-Federal regulation" (H.R. Rep. No. 94-853, at 45 (1976):

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a). Plaintiffs' claims would impose state law requirements "different from, or in addition to" federal requirements governing disclosures in premarket clearance notifications, for the reasons set forth below.

B. Federal Premarket Clearance Regulations Requiring Submission of Proposed Labeling Describing a Device's "Intended Use" Do Not Require Disclosing the Applicant's Subjective Intent Regarding Possible Off-Label Uses

1. The Federal Premarket Clearance Regulations at Issue Require the FDA to Classify the Device Under Review

The FDA authorized the marketing of the orthopedic bone screws at issue in this case through the Section 510(k) premarket clearance process. This process is established by, and named after, Section 510(k) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 360(k), under

which prospective new manufacturers present information about the device to the FDA to obtain marketing authorization. The FDA uses this information to determine whether the device under review is "substantially equivalent" to a predicate "preamendment" device marketed before the MDA were adopted in 1976. The FDA authorizes marketing if the devices are substantially equivalent and denies clearance if they are not. *See* 21 C.F.R. § 807.100.

When it determines that a device is substantially equivalent, the FDA assigns it to the same regulatory classification as its preamendment predicate. The FDA has classified preamendment devices into one of three regulatory categories based upon questions they raise about safety and effectiveness. Class I devices are those presenting the least risk, and are regulated to provide reasonable assurance of safety and effectiveness through general controls. Class II devices are those requiring additional special controls, such as performance standards and specific guidelines, to provide such assurance. Finally, Class III devices are those presenting risks requiring full premarket clearance to provide such assurance. 21 U.S.C. § 360c. By determining that the bone screws at issue in this case were entitled to Section 510(k) clearance, the FDA assigned them to the same classification applicable to their preamendment predicates.

One of the purposes of this classification procedure and substantial equivalence review is to give manufacturers of postamendment devices "the freedom to compete, to a limited degree, with and on the same terms as manufacturers of medical devices that existed prior to 1976." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 494 (1996). Such "preamendment" devices are exempt from premarket clearance requirements (unless they have been classified in Class III and the FDA promulgates a regulation requiring otherwise). *See* 21 U.S.C. § 360e(a)(1). The Section 510(k) process ensures that

manufacturers of such devices do not "monopoliz[e] the market" to the detriment of manufacturers of substantially equivalent postamendment devices. *See Medtronic*, 518 U.S. at 478.

2. The FDA's Substantial Equivalence Review Includes an Evaluation of the Device's Functional Capability, Termed "Intended Use," Described in Proposed Labeling

In order to obtain Section 510(k) clearance, a manufacturer must demonstrate (among other things) that its device can perform the same therapeutic function as a specific preamendment device. The regulatory term of art for this therapeutic function is "intended use." FDA accordingly employs the term intended use to designate "what the device does" and to "refer[] to the functional capability of the device." U.S. Dept. of Health and Human Services, *Medical Device Labeling – Suggested Format and Content* (Apr. 25, 1997) at 5.

The FDA determines whether the functional capabilities of the devices are the same by reviewing the device description and by comparing statements in the labeling of the preamendment device with statements in the proposed labeling of the device under review. *Guidance on the Center for Devices and Radiological Health's Premarket Notification Review Program* (June 30, 1986) (K86-3) at 5. The labeling need not be identical. *Id.* The agency makes the comparison by examining (among other things) labeling statements regarding "physiological purpose, . . . condition or disease to be treated or diagnosed, professional or lay use, parts of the body or types of tissue involved, [and] frequency of use." *Id.* If this analysis establishes that the device under review does not have the same functional capability as a preamendment device, it obviously cannot be substantially equivalent. Therefore FDA's regulatory practice in 1986,

when it cleared the devices at issue for marketing, was to deny premarket clearance if this review of labeling, together with the physical device description, indicated that the device under review had a different functional capability (termed intended use) than the predicate preamendment device. *Id.* at 4-5, 7. Congress codified this practice in 1990 and 1997, when it enacted legislation specifying that the agency's determination "of the intended use of a device shall be based upon the proposed labeling" and that a device must have "the same intended use as the predicate device" to be substantially equivalent. 21 U.S.C. § 360c(i)(1)(E)(i), (1)(A) (Supp. IV 1998).

3. Required Statements of Intended Use Are Statements Regarding the Functional Capabilities of the Device Under Review And are Not Representations of Subjective Intent Regarding the Actual Uses the Device Will Perform Following Premarket Clearance

In this case, the preemptive federal requirements "applicable . . . to the device" (21 U.S.C. § 360k(a)(1)) are those that govern submission of information regarding a device's "intended use" to the FDA in connection with a Section 510(k) premarket clearance notification. The version of the FDA's regulations in effect during the relevant time period (like the current version) required submitting "[p]roposed . . . labeling . . . sufficient to describe the device [under review and] its intended use . . ." 21 C.F.R. § 807.87(e) (1986). The purpose of this submission requirement is solely to allow the FDA to determine whether the new device's functional *capabilities* as described in the proposed labeling are the same as those set forth in the labeling of a preamendment device. The description of intended use in a Section 510(k) notification therefore is *not a representation of the manufacturer's subjective intent*

about what actual uses of the device may occur following clearance.[2]

Other provisions of the FDCA, FDA regulations and agency pronouncements all confirm this understanding of "intended use." *First*, the FDCA indicates that the FDA's review of Section 510(k) statements regarding intended use is exclusively for purposes of a labeling comparison between the device under review and its preamendment predicate — and is not an inquiry that extends into issues other than substantial equivalence. 21 U.S.C. § 360c(i) requires that the FDA's determination of intended use in its substantial equivalence analysis "shall be based upon the proposed labeling." The legislative history of the same provision confirms that this determination from the labeling "will be controlling," and that the relevant consideration is "whether or not the proposed labeling of the newer device is compatible with the labeling of the predicate device."

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2 At the time the bone screws at issue were cleared for marketing in 1986, the FDA was well aware that medical professionals may legally use devices cleared through the Section 510(k) process for uses that are not described in the labeling. *See, e.g.*, James M. Beck & Elizabeth D. Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 Food & Drug L.J. 71 (1993) at 76-80. The agency has recognized that such "off-label" uses are legitimate and important for the public health, because cutting-edge therapies are frequently developed through "off-label" uses of devices cleared by the FDA for a different use. *See, e.g.*, Pet. App. at 28a n.1. Judge Cowan's dissent below properly explained that "[t]he FDA and the medical community have long recognized the importance of doctors' off-label uses of medical products (uses not indicated on the label or approved by the FDA)." Pet. App. at 28a.

S. Rep. No. 105-43, at 27 (1997).[3] Accordingly, the subjective intent of the applicant regarding possible uses not listed in the proposed labeling is simply not relevant to the Section 510(k) submission or its review by the FDA.

Second, by confirming that statements in proposed labeling are the basis for the agency's comparison of intended use between the device under review and its preamendment predicate, Congress necessarily also has indicated that information about other possible uses of either device (not listed in their labeling) is *not* relevant to substantial equivalence. The legislative history of 21 U.S.C. § 360c(i) expressly confirms that "[n]o considerations outside of the proposed labeling for the Section 510(k) device should bear on the question" of substantial equivalence. S. Rep. No. 105-43 at 27. Because off-label uses are not relevant to the substantial equivalence determination, and the sole purpose of a Section 510(k) notification is to demonstrate substantial equivalence, an applicant for Section 510(k) clearance has no obligation to notify the FDA about possible off-label uses. To conclude otherwise would place a duty on the manufacturer of a new device to disclose every possible off-label use of which it is aware. The FDA regulations

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[3] Although enacted in 1997, this statement of congressional intent simply codifies agency practice extending back at least as early as 1986, when the FDA granted premarket clearance for the orthopedic bone screws at issue. *See Determination of Intended Use for 510(k) Devices – Guidance for Industry and CDRH Staff* (Jan. 30, 1998) at 1 (statutory requirement "not different from the manner in which 510(k)s have traditionally been reviewed"); *Guidance on the Center for Devices and Radiological Health's Premarket Notification Review Program* at 10 n.3 (intended use ordinarily determined by reference to labeling or promotional claims).

specifying the contents of a Section 510(k) notification simply do not require such a disclosure. *See* 21 C.F.R. § 807.87 (1986).[4]

Third, FDA's regulations confirm that a statement of intended use is not a statement of subjective intent. To the contrary, "the words *intended use[]* . . . refer to the objective intent of the persons legally responsible for the labeling of the devices." 21 C.F.R. § 801.4. "Intended use" is a term of art that does not encompass the subjective intent of the applicant for premarket clearance.

Finally, the submission of proposed labeling containing a statement of intended use is not a representation that the device will ever *actually* be manufactured or sold for *any* purpose. The FDA has made clear that there is "no requirement that an actual prototype of a device must be manufactured" in order to receive premarket clearance. *Premarket Notification: 510(k) Regulatory Requirements for Medical Devices* (Feb. 1986) at 2. Furthermore, *amicus curiae* is familiar with a number of instances in which the

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[4] 1997 amendments to the Federal Food, Drug, and Cosmetic Act do require that in order to obtain Section 510(k) clearance, a 510(k) notification submitter may be required to modify its label to describe certain off-label uses that "could cause harm" and to specify limitations on such uses. 21 U.S.C. § 360c(i)(E). This provision does not impose any requirement to *disclose* possible off-label uses in the Section 510(k) notification in the first instance; indeed, the statute assumes that such uses are "not identified in the proposed labeling" submitted with the device. *Id.* The provision instead simply allows the agency, if it has information regarding potentially harmful off-label uses from *any* source, to require labeling warnings as a condition of premarket clearance. And in any event, the provision does not apply to the clearances at issue in this case, which were obtained in 1986.

agency has cleared a device for marketing as substantially equivalent yet the manufacturer has decided not to manufacture or sell the device in the marketplace. The Section 510(k) process only determines whether marketing is *permissible* because of similarities in functional capability between the device under review and the predicate device. The process does not seek to determine whether marketing will in fact occur, and if so, what therapeutic use will actually be made of the device.

C. Plaintiffs' Claims Would Impose State Law Requirements Different From, or in Addition to, Federal Requirements by Requiring a Premarket Clearance Applicant to Disclose its Subjective Intent Regarding Possible Off-Label Uses

Plaintiffs' claims are preempted, because they would impose state law requirements "different from, or in addition to," the federal requirements explained above requiring submission of proposed labeling describing intended use. Although the federal requirements do not require disclosure of the applicant's subjective intent regarding off-label uses for the reasons described above, the premise of Plaintiffs' claims is that state law does impose a duty to make such disclosures. A majority of this Court confirmed in *Medtronic* that state tort law duties are state "requirements" within the meaning of the MDA express preemption provision. *Medtronic*, 518 U.S. at 503-04 (Opinion of Breyer, J.), 509 (Opinion of O'Connor, J.); *see also Geier v. American Honda Motor Co.*, 120 S. Ct. 1913, 1918, 1934 (2000) (*Medtronic* recognized that reference to state "requirement" in express preemption provision may include common law duties). Because they would require disclosures to the FDA that applicable federal requirements do not, these state requirements are obviously "different from, or in addition

to," the federal requirements. Accordingly, the Court should hold that Plaintiffs' claims are expressly preempted.

II. THE MEDICAL DEVICE AMENDMENTS IMPLIEDLY PREEMPT PLAINTIFFS' STATE LAW CLAIMS FOR FRAUD ON THE FDA

A plurality of this Court expressly recognized in *Medtronic* that in a future case, it might conclude that tort claims involving a medical device were "preempted under conflict preemption analysis." *Medtronic*, 518 U.S. at 503. This is such a case. Under the doctrine of implied "conflict" preemption, state law is invalid if it "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941). This Court has recognized that state law presents such an obstacle if it "interferes with the methods by which the federal statute was designed to reach" its goals. *International Paper Co. v. Ouellette*, 479 U.S. 481, 494 (1987). Applying these standards, the Court should hold that the MDA impliedly preempt Plaintiffs' state law claims.

A. Preserving Fraud on the Agency Claims Would Interfere With the FDA's Statutory Responsibility to Bring Needed Therapies to Patients As Quickly As Possible

Preserving fraud on the agency claims from preemption would interfere with the FDA's statutory responsibility to "promote the public health by . . . taking appropriate action on the marketing of regulated products in a timely manner." 21 U.S.C. § 393(b)(1). Because federal law prohibits manufacturers from distributing most new medical devices without prior clearance from the FDA (*see, e.g.*, 21 U.S.C. §§ 360e, 360(k) (1994 & Supp. 1998)), delays in premarket clearance profoundly affect patients' health by postponing

their access to innovative device therapies. The FDA has recognized the importance of streamlining its premarket clearance processes to "bring needed therapies to patients as quickly as possible." *Hearing Before the Subcomm. On Oversight & Investigations of the House Comm. On Commerce* (Sept. 23, 1997) (statement of Michael A. Friedman, Lead Deputy Commissioner, FDA). Yet fraud on the agency claims such as those at issue in this case would hamper the FDA's ability to meet its statutory mandate to provide prompt premarket clearance for devices.

1. Fraud on the Agency Claims Would Delay Premarket Clearance by Entangling FDA Personnel in Litigation Between Private Parties

Until the Third Circuit's decision in this case, most lower courts had held (both before and after *Medtronic)* that the MDA preempt claims for fraud on the FDA. *See* Pet. for Cert. at 11-15. If such claims were instead preserved from preemption, as the Third Circuit held, they would increasingly cause delays in premarket clearance by entangling FDA personnel in litigation between private parties. The Solicitor General's *amicus curiae* brief in support of the Petition for Certiorari properly concluded that such litigation would "pose a significant potential for diverting an agency's resources and for distorting its internal decisionmaking processes." Br. for the United States as Amicus Curiae at 17.

Fraud claims such as those at issue here assert that misrepresentations were made to FDA officials responsible for premarket clearance decisions, who in turn authorized marketing of a medical device in reliance on the misrepresentations. These officials obviously would be critical witnesses to the alleged fraud in a tort suit, because their personal knowledge typically would determine whether

a misrepresentation occurred, and if so, whether it affected premarket clearance of a medical device. Given their unique knowledge of the facts at issue in a fraud on the agency claim, FDA officials would be important witnesses for both the plaintiff and defendant. Indeed, in the present case, Plaintiffs claim that Petitioner misled agency officials, yet Petitioner contends that its course of action (now alleged to be fraudulent) was *suggested* by the FDA. *See* Pet. for Cert. at 17 n.8. For both parties, the witnesses who could provide the best evidence to resolve factual disputes like this one would be the FDA officials who reviewed and acted on the manufacturer's premarket clearance submissions.

Because they would be such important witnesses in fraud on the agency claims, FDA officials would be vulnerable to entanglement in tort litigation. Although the FDA, like other agencies, has promulgated "housekeeping" regulations that purport to restrict its obligation to respond to third party subpoenas issued in litigation between private parties, *see* 21 C.F.R. § 20.1, those regulations do not guarantee the agency any protection against involvement in tort suits. The regulations themselves authorize testimony if the public interest so requires. *See id.; In re U.S. Bioscience Sec. Litig.*, 150 F.R.D. 80 (E.D. Pa. 1993) (enforcing subpoenas for deposition testimony of FDA employees in private securities litigation).

Furthermore, at least since the Ninth Circuit's decision in *Exxon Shipping Co. v. Department of Interior*, 34 F.3d 774 (9th Cir. 1994), the lower courts increasingly have cast substantial doubt on the validity of such housekeeping regulations. In *Exxon*, the Ninth Circuit held that five federal agency heads could not rely on their agencies' housekeeping regulations to prevent subordinate employees from testifying pursuant to third party deposition subpoenas. The Ninth Circuit rejected the argument that this Court's decision in

United States ex rel. Touhy v. Ragen, 340 U.S. 462 (1951) permitted federal agencies to refuse to allow their employees to respond to valid third-party subpoenas by invoking such regulations. *Exxon*, 34 F.3d at 778.[5] The court concluded that just like any other witness, a federal employee witness is required to comply with a federal court subpoena under the standards set forth in Fed. R. Civ. P. 45. *Id.* at 779. Following *Exxon*, numerous other lower courts also have held that government agencies — including the FDA — may not rely on housekeeping regulations to withhold information sought through third-party subpoenas. *See, e.g., Houston Business Journal, Inc. v. Office of Comptroller of Currency*, 86 F.3d 1208, 1212 (D.C. Cir. 1996) (housekeeping regulations do not authorize withholding subpoenaed documents in conflict with Fed. R. Civ. P. 45); *Connaught Labs., Inc. v. SmithKline Beecham*, 7 F. Supp.2d 477 (D. Del. 1998) (rejecting restrictions of FDA housekeeping regulations and enforcing subpoenas for testimony of FDA employees in patent litigation between private parties).

Once subpoenas were issued in a fraud case, the drain on the time and resources of agency personnel required for

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5 In *Touhy*, the Court held that an FBI official could not be held in contempt for obeying an order by his superior — the Attorney General — to refuse production of documents pursuant to a third-party subpoena. *Touhy* therefore addressed the question whether the Attorney General, as head of an agency, had authority to "centraliz[e] determination as to whether subpoenas *duces tecum* will be willingly obeyed or challenged" by implementing housekeeping regulations that "withdraw from his subordinates the power to release department papers." 340 U.S. at 467-68. The Court expressly refused to reach the question whether the agency itself had a "privilege against disclosure" (*id.* at 468, 469 & n.9) allowing it to "refuse to produce government papers." *Id.* at 469.

subpoena responses would be substantial. The scope of relevant testimony and documents potentially would be quite broad, because every communication between the manufacturer and the FDA regarding premarket clearance could be a source of evidence in a case alleging fraud on the agency, and such communications are numerous; the FDA's review of premarket clearance submissions is a collaborative process between the manufacturer and the agency, involving frequent dialog over a period of months or even years.

For example, the agency has long encouraged early meetings between manufacturers and FDA officials to exchange information about a new device even before the FDA has approved clinical studies that may be required for eventual premarket clearance. *See Guidance on IDE Policies and Procedures* at 1 (Jan. 20, 1998) <http://www.fda.gov/cdrh>; *Goals and Initiatives for the IDE Programs* IDE Mem. #D95-1, at 2 (July 12, 1995) <http://www.fda.gov/cdrh/d951.htm1>. In 1997, Congress endorsed a similar interactive process by amending the FDCA to require the FDA, upon written request, to meet with the applicant for a premarket approval application ("PMA") within 100 days after the PMA is filed. 21 U.S.C. § 360e(d)(3). The agency does not limit itself to this required meeting and goes "beyond the [statutory] requirements by encouraging 'exploratory' meetings very early in the premarket review process and continued interactions throughout the review process." *FY 2000 Budget Request* at 1 <http://www.fda.gov/oc/oms/ofm/budget/devnctrtab.htm>. The FDA has agreed "to communicate with each firm at least every four weeks subsequent to the 100-day meeting." *FDA/CDRH Annual Report FY 1998* at 1 <http://www.fda.gov/cdrh/index.html>.

A fraud on the agency claim would potentially require FDA personnel to respond to discovery concerning each of

these communications, thereby diverting substantial resources from review of premarket clearance notifications. Distracting agency officials from their critical device review functions would undermine the congressional purpose by retarding the clearance of promising new therapies that could substantially improve the public health.

2. Fraud on the Agency Claims Would Delay Premarket Clearance by Creating Incentives to Burden the FDA With Needless Submissions of Information

If fraud on the agency claims were preserved from preemption, they also would delay premarket clearance by creating incentives to burden the FDA with additional submissions of information. Manufacturers would attempt to protect themselves against fraud liability by submitting to the agency all information that is even arguably relevant to product clearance, to guard against later allegations that there were material omissions in communications with the agency. *See* Pet. for Cert. at 18.

These additional information submissions would be unnecessary. For example, in the present case, the agency had no need for additional information to determine whether it had been defrauded. Only three months passed between the premarket clearance notification that plaintiffs allege revealed defendants' true subjective intended use (spinal surgery) and the notification that plaintiffs allege fraudulently misrepresented the intended use as for the long bones in the arms and legs. Pet. App. at 5a. The FDA officials responsible for reviewing these applications manifestly had full notice that the intended use had been changed — and according to the petition had in fact *encouraged* the change (Pet. for Cert. at 17 n.8) — at a time when it was well known at the agency that "[i]n practice, surgeons often use orthopedic screws which FDA has cleared for other

purposes" in spinal surgery instead. *See FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 Food & Drug L.J. at 77 (citing FDA, Update on Pedicle Screws).

Though needless, the additional information submissions would have a deleterious effect on the FDA's product clearance work. Once the information was submitted, it would need to be reviewed by FDA personnel who already have limited budgetary resources. Furthermore, in recent years, the number of FDA employees in the Office of Device Evaluation ("ODE") — the office responsible for reviewing premarket clearance applications — has steadily fallen. 1996 ODE Annual Report at 1; 1997 ODE Annual Report at 1; 1998 ODE Annual Report at 2, *supra*; 1999 ODE Annual Report at 2. Increasing the amount of information for these officials to review would increase product clearance times and delay the marketing of innovative therapies for patient use.

The tort system would create this effect after the FDA, both on its own initiative and with congressional urging, has made great strides to reduce clearance times by *diminishing* the information required to be submitted for agency review. *See, e.g.*, 21 U.S.C. § 360c(a)(3)(C) (requiring the FDA to consider "whether the extent of data that otherwise would be required for approval of the application with respect to effectiveness can be reduced through reliance on postmarket controls"). For example, the FDA now requires submission of less information for Section 510(k) notifications regarding low risk devices (because clearance decisions are based primarily on descriptive information and a labeling review) than it does for high risk devices (for which clearance decisions rely on performance data). *The New 510(k) Paradigm* at 3 (Mar. 20, 1998) <http://www.fda.gov/cdrh/ode/parad510.html>. The agency also requires more

information in a Section 510(k) notification seeking initial clearance for a device than it does for a notification seeking clearance for a change in a previously marketed device. *FY 2000 Budget Request* at 2, *supra*. To reduce submission requirements regarding Section 510(k) notifications further, the FDA also permits manufacturers to certify compliance with certain material and performance standards in lieu of submitting information demonstrating compliance. *Id.* Because it has streamlined the submission process, the FDA review time for Section 510(k) notifications during fiscal year 1998 was only *half* what it was only four years earlier. *FDA/CDRH Annual Report FY 1998* at 7, supra.

Fraud claims of the type at issue in this case would undermine this important progress, interfering with the statutory purpose of accelerating clearance of critical new devices. In so doing, such claims would "stand[] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" (*Hines*, 312 U.S. at 67) — a circumstance that this Court has long viewed as giving rise to implied preemption of state law.

B. Preserving Fraud on the Agency Claims Would Interfere With the FDA's Authority to Remedy Fraud in its Premarket Clearance Processes

Preserving fraud on the agency claims also would frustrate the congressional purpose by interfering with the FDA's authority under federal law to remedy fraud in its premarket clearance processes. Plaintiffs allege that the agency was defrauded, even though the agency — with all relevant facts before it — does not appear to agree. The Supremacy Clause does not allow Plaintiffs to invoke state law to meddle with the FDA's unique responsibility to remedy fraud in its premarket clearance processes.

Under federal law, the agency has extensive tools at its disposal to root out and punish fraud in its premarket clearance processes. The agency proceeds under its "fraud policy" to investigate "acts such as submitting fraudulent applications, making untrue statements of material facts, or giving or promising bribes or illegal gratuities [that] may call into question the integrity of some or all of the applicant's submissions to the agency." 56 Fed. Reg. 46,191, 46,199 (1991). If fraud is uncovered, the FDA exercises its authority "under applicable statutes and regulations, to refuse to approve the application (in the case of a pending application) or to proceed to withdraw approval (in the case of an approved application)." *Id.* at 46,200. The FDA also refers fraud cases for criminal prosecution by the Department of Justice, because violation of the FDCA's prohibitions with "intent to defraud or mislead" is a felony. 21 U.S.C. §§ 331, 333(a)(2); *see also United States v. Cambra*, 933 F.2d 752, 755 (9th Cir. 1991) (FDCA felony provision prohibits fraud on government enforcement agencies). The federal Sentencing Guidelines include a sentencing enhancement for FDCA felony violations involving fraud if the government obtains a conviction. U.S.S.G. §§ 2N2.1(b)(1); 2F1.1.

In this regulatory scheme, with its "general prohibition on non-Federal regulation" (H.R. Rep. No. 94-853 at 45), the proper role of a private party is to *refer* alleged frauds to the agency for investigation, not to act as a private attorney general pursuing independent remedies under state law. For example, the FDA's "Citizens Petition" process allows any person to request the agency to withdraw a product clearance obtained through fraud. *See* 21 C.F.R. § 10.30. Plaintiffs are well aware of this process, having filed a Citizens Petition (with 1,000 pages of supporting material) alleging fraud on the agency and seeking withdrawal of one manufacturer's bone screw product clearance. Citizens Petition, FDA

Docket No. 98P-0623 (July 24, 1998). In addition, private parties may bring alleged frauds to the attention of the agency through contacts with FDA enforcement personnel. The Supremacy Clause, however, precludes such parties from employing state law to pursue their own private theories of fraud, thereby undermining the enforcement scheme intended by Congress.

CONCLUSION

For the reasons set forth above, the judgment of the court of appeals should be reversed.

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THE BUCKMAN COMPANY,
Petitioner,

v.

PLAINTIFFS' LEGAL COMMITTEE,
Respondent.

On Writ of Certiorari to
the United States Court of Appeals
for the Third Circuit

BRIEF AMICUS CURIAE OF PUBLIC CITIZEN IN SUPPORT OF RESPONDENT

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BRIEF AMICUS CURIAE OF PUBLIC CITIZEN IN SUPPORT OF RESPONDENT

INTEREST OF AMICUS[1]

Public Citizen is a nationwide non-profit advocacy group with more than 150,000 members. It appears before Congress, administrative agencies, and the courts on a wide range of issues, including preservation and enhancement of the state-law civil justice system. Of particular relevance to this case, Public Citizen attorneys have represented plaintiffs and appeared as an amicus curiae in many cases presenting the question whether the Medical Device Amendments to the Food, Drug, and Cosmetic Act ("FDCA") expressly or impliedly preempt state damages claims. For example, Public Citizen attorneys represented the plaintiffs in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), which figures prominently in the briefs filed in this case. Public Citizen has also represented plaintiffs and amici in cases involving the preemptive effect of other federal regulatory statutes on state-law damages actions. *See, e.g., Freightliner Corp. v. Myrick*, 514 U.S. 280 (1995) (National Motor Vehicle Safety Act); *Hart v. Bayer Corp.*, 199 F.3d 239 (5th Cir. 2000) (Federal Insecticide, Fungicide, and Rodenticide Act); *Roberts v. Florida Power & Light Co.*, 146 F.3d 1305 (11th Cir. 1998) (Atomic Energy Act). Thus, Public Citizen has a longstanding interest in the issue presented in this case.

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[1] Pursuant to Rule 37.6 of this Court, amicus states that no party had any role in writing this brief and that no one other than amicus or its counsel made a monetary contribution to the preparation or submission of this brief. This brief is being filed in accordance with a consent agreement regarding amicus briefs entered into by both parties, which has been filed with the Clerk.

STATEMENT OF CASE AND SUMMARY OF ARGUMENT

Before AcroMed Corporation, which is not a party to this case, could market its pedicle screws, the Medical Device Amendments of 1976 required it to obtain permission from the Food and Drug Administration ("FDA"). A necessary element of its application was a statement of the intended use of the product. AcroMed initially proposed to market the screws for use in the pedicles of the spine. On two occasions, the FDA denied marketing clearance for that use. Thereafter, petitioner Buckman, acting as AcroMed's agent, submitted an application that sought clearance for the pedicle screws' components parts and stated that the intended use of the devices was for fixation of the long bones of the arms and legs. According to the complaint, however, Petitioner knew that AcroMed intended to market the devices exclusively for use in the pedicles. Based upon the misrepresentations of intended use, the FDA granted marketing clearance, the devices were implanted in patients' backs, and patients were injured.

Fairly read, the complaint strongly suggests that AcroMed, as the direct beneficiary of the fraudulent approval, was a full partner in the scheme. JA 13-21. However, because all of the claims against AcroMed have been resolved by a court-approved class action settlement, only the claim against the agent Buckman remains. Since Buckman's role in this matter involved only the fraudulent submission to the FDA, fraud is the only claim asserted against Buckman. In contrast, plaintiffs asserted numerous product liability claims against AcroMed, including the state-law product liability claims typically alleged in such cases. The district court decided that, no matter what proof respondent Plaintiffs' Legal Committee could offer, federal law preempted the claim against Buckman. The court of appeals reversed, and this Court granted review.

Although the question presented encompasses both express and implied preemption, the inapplicability of express preemption to the claim at issue follows directly from *Medtronic*, as the United States demonstrates in its amicus brief. Accordingly, this brief will not address express preemption.

As to implied preemption, the arguments put forth by Petitioner and the United States should be rejected and the court of appeals' decision affirmed. The initial flaw in the implied preemption arguments of Petitioner and the United States is that they seek to avoid the presumption against preemption by recasting this claim as one in an area of traditional federal interest. This case, however, is a damages case alleging a traditional state-law cause of action for fraud. The only unusual wrinkle is the means by which the fraud was perpetrated—misrepresentations to the FDA, whose regulatory clearance was required as a prerequisite to marketing. That wrinkle does not alter the basic preemption analysis because this Court's reasons for the presumption against preemption still apply.

Seeking to identify a conflict between Respondent's claim and a federal interest, both Petitioner and the United States offer only broad statements about the implications of allowing this case to go forward on the merits. These concerns are so general and ill-defined that they would also apply, for example, to claims of design defect, manufacturing defect, or failure to warn, and in cases involving drugs, food additives, and other regulated products. Such broad preemption of state common-law claims is unjustified by any scenario offered by Petitioner or the United States and is flatly at odds with this Court's Supremacy Clause jurisprudence. Moreover, this case does not present a proper vehicle for expanding the Court's

implied preemption doctrine because in the usual product liability claim—brought against the manufacturer, not the manufacturer's agent—fraud-on-the-FDA claims will not have practical significance. This Court should therefore reject Petitioner's invitation to such a significant departure from federalism principles and implied preemption jurisprudence.

ARGUMENT

I. RESPONDENT'S CLAIM DOES NOT INTERFERE WITH ANY FEDERAL INTEREST AND, THUS, IS NOT IMPLIEDLY PREEMPTED.

A. The Presumption Against Preemption Applies In This Case Because The Claim At Issue Implicates Traditional State Concerns.

The Supremacy Clause provides the constitutional authority for the proposition that conflicts between federal and state law are resolved in favor of federal law. *See McCulloch v. Maryland*, 4 Wheat. 316, 427, 4 L. Ed. 579 (1819); *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992). The Supremacy Clause is restricted by other principles implicit and explicit in the constitutional plan. In particular, the Tenth Amendment provides: "The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people."

In light of the constitutional imperative of federalism, a party seeking preemption of state law bears a heavy burden. There is a strong presumption *against* preemption that may be overcome only by "clear and manifest" congressional intent to the contrary. *Hillsborough County, Florida v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 715 (1985); *see also Hawaiian Airlines, Inc. v. Norris*, 512 U.S. 246, 252 (1994);

Wisconsin Public Intervenor v. Mortier, 501 U.S. 597, 605, 611 (1991).

Thus, "[c]onsideration under the Supremacy Clause starts with the basic assumption that Congress did not intend to displace state law." *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981). Put differently, "[p]reemption of state law by federal . . . regulation is not favored 'in the absence of persuasive reasons—either that the nature of the regulated subject matter permits no other conclusion, or that Congress has unmistakably so ordained.'" *Chicago and North Western Transportation Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311, 317 (1981) (quoting *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142 (1963)). The presumption against preemption is even stronger where "Congress [has] legislated . . . in a field which the States have traditionally occupied, [involving] the historic police powers of the States." *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). In other words, the presumption is "that state and local regulation of health and safety matters can constitutionally coexist with federal regulation [because] the regulation of health and safety matters is primarily and historically a matter of local concern." *Hillsborough County*, 471 U.S. at 716, 719. This presumption applies when a defendant is seeking preemption of state tort remedies because, in that situation, preemption would displace the historic power of the states to protect the health and safety of their citizens. *See, e.g., Medtronic*, 518 U.S. at 484-86.

Moreover, as in this case, where the allegedly preemptive federal regulatory scheme does not itself provide a damages remedy and preemption would leave injured individuals without any state *or* federal remedy against the tortfeasor, this Court has ascribed preemptive intent to Congress only in the most compelling circumstances. *See*

English v. General Electric Co., 496 U.S. 72, 87-90 (1990); *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984).

Both Petitioner and the United States acknowledge these principles. They argue, however, that the presumption against preemption does not apply here because the fraud claim at issue intrudes on an area of federal, not state, concern. This reasoning is flawed, primarily because Petitioner's claim *does* arise out areas of traditional state concern. The claim is based on state common-law fraud principles and seeks common-law damages for injuries suffered by individuals that would not have occurred but for the allegedly fraudulent conduct. The contrary view of Petitioner and the United States is based on the artifice that the truthful reporting obligations imposed by the FDCA are intended to serve only government interests, not the interests of the citizens who use the products approved for marketing by the FDA.

The statute and regulations pursuant to which the FDA acts, however, including the requirement of truthful submissions, are intended to protect patients who use drugs and medical devices, not to protect a government interest in truthful reporting as an end in itself. The state's interest, as implicated by Respondent's claim, is to compensate injured patients. In other words, both the state damages action and the federal truthfulness requirements are intended to protect patients' health and safety. *See Medtronic*, 518 U.S. at 485 (recognizing historic state interest in matters of health and safety). Therefore, the state-law claim and the federal regulations are complementary, not conflicting.

Arguing that the presumption against preemption does not apply in cases that implicate "an area of paramount federal concern," US Br. 19, Petitioner and the United States rely on *Boyle v. United Technologies Corp.*, 487 U.S. 500 (1988). Pet.

Br. 31; US Br. 19. There, the plaintiff had brought a damages action for injuries caused by a product that the defendant had manufactured pursuant to specifications dictated by a contract with the United States. The Court held that design defect suits, although an area of traditional state concern, implicate "unique" federal interests where the claims involve "obligations to and rights of the United States under its contracts" and "civil liabilities arising out of the performance of federal procurement contracts." *Boyle*, 487 U.S. at 504-06. The outcome of such a lawsuit, the Court held, even one between private parties, would directly affect the government's interests, either the contractor's willingness to manufacture the design specified or the price charged. *Id.* at 507.

In contrast, this case presents no such "unique" federal interests. Not even the United States suggests that the outcome of the lawsuit would affect the government interest it identifies—the FDA's ability to obtain accurate information from regulated entities. US Br. 18. *Cf. Pacific Gas & Energy v. Energy Resources Comm'n*, 461 U.S. 190 (1983) (no preemption of state regulation of economic aspects of atomic power plants where federal government occupied field of atomic safety but not economic effects of atomic power plants).

Instead, *Miree v. DeKalb County*, 433 U.S. 25 (1977), is the analogous case here. There, the plaintiffs sued the County for, among other things, breach of contract for maintaining a dump adjacent to an airport in violation of a contract between the County and the United States. The plaintiffs alleged that they were third-party beneficiaries to the contract, that the dump attracted birds that had caused an airplane crash, and that plaintiffs were entitled to damages for injuries suffered in the crash. The court of appeals had held that federal common law was applicable to the breach of contract claim. It had reasoned that the fact that the United

States was a party to the contract at issue, which was entered into pursuant to a federal statute, "necessit[ated] uniformity of decision." This Court reversed, citing the fact that the resolution of the claim would have no direct effect on the United States or its Treasury. The instant case is no different. Federal involvement in the factual background of the case does not support the conclusion that federal interests are at stake in this state-law damages claim.

B. Allowing The Claim To Proceed Will Not Harm Any Legitimate Federal Interest.

Whether or not the presumption against preemption of state law applies, the claim is not preempted because it does not conflict with any federal interest. The implied preemption arguments of Petitioner and its amici stray far from the facts of this case and are inconsistent with the preemption principles established by the Constitution and this Court. Moreover, their theories for a finding of implied preemption are so broad as to apply to a significant portion of product liability law—to design defect claims, manufacturing claims, and fraud claims, for example—even in situations where the agency subsequently discovered fraud and took action against the wrongdoer.

The United States points to three federal interests in support of implied preemption of Respondent's fraud-on-the FDA claim, and its arguments encompass those of Petitioner. Although the United States indicates throughout its brief that it intends to address only fraud-on-the FDA claims, its suggested bases for conflict preemption could be applied broadly to many sorts of product liability claims. As discussed below, however, none of the Government's three points justifies a finding of preemption here.

1. Attempting to fashion a conflict between Respondent's state-law claim and the FDA's interests, the United States identifies a federal interest in "regulating information that a regulated entity must submit to the FDA." US Br. 23. By its very nature, however, a claim premised on allegations that the FDA's own regulations were violated is consistent with the FDA regulations setting forth the nature of required submissions.

The argument in favor of preemption fares no better when characterized as a conflict with the "interest in permitting FDA to decide for itself whether it has been defrauded and, if so, what remedy to seek." US Br. 21. In this regard, Petitioner reminds the Court that the FDCA does not establish a private right of action. Pet. Br. 36. However, the claim at issue is not brought under the FDCA. It is not a claim to enforce the FDCA. It is a claim under state-law principles and seeks damages for injuries suffered, not by the FDA, but by individual patients. Like a negligence per se claim or the manufacturing and labeling claims at issue in *Medtronic*, state law may recognize a cause of action for violation of state-law duties embodied in a federal statute, even where the federal statute does not create a private federal right of action. *See Medtronic*, 518 U.S. at 495 ("Nothing in [express preemption provision] denies Florida the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements.") (majority decision); *id.* at 513 ("To be sure, the threat of a damages remedy will give manufacturers an additional cause to comply [with federal regulations], but the requirements imposed on them under state and federal law do not differ.") (O'Connor, J., concurring in part and dissenting in part).

Although the United States asserts that allowing Respondent to pursue this state-law claim for damages would

interfere with the FDA's enforcement authority, litigation of the claim would not in fact preclude the FDA from taking any enforcement action in regard to the conduct at issue. Nonetheless, the Government offers three theories to support this purported conflict. None of the three, however, fits within established principles of conflict preemption. Moreover, the breadth of the Government's arguments would nullify *Medtronic* and the Government's own position, expressed in *Medtronic*, in *Smith Industries Medical Systems v. Kernats*, *see* Brief for United States as Amicus Curiae in *Smith Industries Medical Systems v. Kernats*, S. Ct. No. 96-1405 (filed Dec. 1997), and in this case, US Br. 11-12, that the MDA does not expressly preempt the vast majority of damages claims.

First, the United States says the conflict manifests itself in the possibility that juries in different states might reach judgments that differ from the FDA's with respect to whether Petitioner committed fraud. In this case, that possibility is far-fetched because the facts make plain that the FDA does not intend to make any judgment as to Petitioner's alleged fraud. In any event, even if possible, that scenario does not trigger conflict preemption. Indeed, the United States never explains in what way differing state-law verdicts on the question of whether Petitioner's misrepresentations to the FDA caused injury to plaintiffs would present an actual conflict with or impediment to the FDA's ability to enforce its regulations.

Moreover, the possibility that different juries will reach different conclusions based on the same facts is in no way unique to "fraud-on-agency" claims. For example, the possibility of different adjudications on similar facts existed throughout the pedicle screw litigation, as it does in any series of cases arising from toxic torts or product liability claims. That fact alone has no logical connection to the question of implied preemption. *See Silkwood*, 464 U.S. at 256 (accepting

"tension" between conclusion that safety regulation is exclusive federal concern and conclusion that states may award damages based on their own laws of liability).

Because it is not tied to the claim at issue in this case, the United States' argument would swallow much of product liability litigation in cases where the product at issue received federal marketing clearance. For example, the United States itself recognizes that premarket approval of medical devices does not preempt state-law design defect claims, negligent manufacturing claims, or failure-to-warn claims. *See generally* Brief for United States as Amicus Curiae in *Smith Industries Medical Systems v. Kernats*, S. Ct. No. 96-1405 at 14-18. Yet the Government's argument would be equally applicable to such state-law tort claims since those claims also implicate federal regulations as to which the FDA has at least primary enforcement authority. Accordingly, if this Court were to create a new super-category of "conflict" preemption for state-law damages actions based on the possibility that some of those cases would result in decisions different from the one a federal agency might have made (whether or not the agency had made any decision at all), plaintiffs would lose their sole means of obtaining a remedy for injuries caused by new medical devices, drugs, food additives, and other products subject to premarket federal scrutiny.

Second, the United States argues that the FDCA does not envision damages remedies for injured patients and that, therefore, to allow such remedies would "distort" the statute's penalty scheme. US Br. 23. This argument also is stated so broadly as to threaten a significant portion of product liability and personal injury damages claims, including claims that the FDA itself states do not warrant preemption. The FDCA's remedial scheme is directed at punishing wrongdoers and righting regulatory wrongs. *See* US Br. 22 (listing potential

penalties). True, the FDCA does not include a private damages remedy. However, the "FDA's authority to require manufacturers to recall, replace, or refund defective devices is of little use to injured plaintiffs, since there is no indication that the right is available to private parties, the remedy would not extend to recovery for compensatory damages, and the authority is rarely invoked, if at all." *Medtronic*, 518 U.S. at 487 & n.7 (opinion of Stevens, J.). Similarly, although the FDA may impose civil money penalties, 21 U.S.C. § 333(g)(1)(A), that money goes to the federal government, not to injured patients. Thus, far from offering a reason *for* preemption, the Government's point supports a finding *against* preemption. *See also Medtronic,* 518 U.S. at 513 ("Section 360k does not preclude States from imposing different or additional *remedies*, but only different or additional *requirements*.") (O'Connor, J. concurring); *Silkwood*, 464 U.S. at 251 ("Congress would [not], without comment, remove all means of judicial recourse for those injured by illegal conduct.").

In fact, the United States' position on express preemption is consistent with the view that damages actions are not impliedly preempted. Certainly, the Government's amicus briefs in *Medtronic* and *Smith Industries Medical Systems v. Kernats* in no way suggested that the FDA felt threatened by the damages claims at issue in those cases. *See* Brief for United States as Amicus Curiae in *Smith Industries Medical Systems v. Kernats*, S. Ct. No. 96-1405 (filed Dec. 1997); Brief for United States as Amicus Curiae in *Medtronic v. Lohr*, S. Ct. No. 95-754, 1996 WL 118035 (filed Mar. 15, 1996). To the contrary, the United States' brief in *Kernats* argued (at 14-18) that the premarket approval process for medical devices does *not* preempt product liability claims. Yet the United States' argument here, although offered with regard to only a single damages claim, simply has no logical stopping point. To hold

that Respondent's claim is preempted because a damages remedy is not available under the FDCA thus threatens "effectively [to] preclude[] state courts from affording state consumers any protection from injuries resulting from a defective medical device." *Medtronic*, 518 U.S. at 487.

Third, the Government asserts that Respondent's state-law claim would interfere with the FDA's discretion to decide which, if any, statutory remedy to pursue. Again, the Government fails to tie this argument to the claim at issue. The same argument could be made for all sorts of state-law damages actions involving injuries caused by regulated products. Moreover, the Government misunderstands the nature of a state-law damages action such as the fraud claim here by suggesting that the action seeks to remedy an offense against the FDA. Such claims do not seek to vindicate an institutional government interest in truthful submissions; they seek remedies for injuries suffered by consumers. Although Petitioner made the alleged misrepresentations here to the FDA, the FDA was not harmed. Patients were harmed. Although labeled a claim for "fraud on the FDA," the victim of the fraud was not the FDA. The victims were the patients who used the device, thereby relying on the misrepresentations to their detriment. JA 21 (¶133). That is, by lying to the FDA, Petitioner effectively lied to the patients who subsequently used the product.

The story of the Bjork-Shiley conveco-concave heart valve ("C/C valve") illustrates that allowing claims such as Respondent's to go forward does not threaten to interfere with the FDA's interests. In 1979, the FDA granted to Shiley, Inc. premarket approval for the C/C valve. *Michael v. Shiley, Inc.*, 46 F.3d 1316, 1320 (3d Cir.), *cert. denied*, 516 U.S. 815 (1995). Throughout the next 6½ years, the FDA grew increasingly concerned about the valve's numerous reported fractures. At

the same time, Shiley repeatedly attempted to thwart FDA efforts to regulate and monitor the C/C valve by delaying required reporting, failing to notify the FDA prior to implementing new tests, failing to submit PMA supplements in a timely manner, and implementing changes prior to substantiation by sufficient testing. *See* FDA Management and Enforcement, Hearing Before the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce, House of Representatives, 1st Sess. 2 (Sept. 12, 1991). Eventually, Shiley withdrew the valves from the market and, on November 24, 1986, ceased all production of C/C valves. *Michael v. Shiley*, 46 F.3d at 1321. Although the FDA had the authority to require the manufacturer to repair or replace the device or to take other actions, *see* 21 U.S.C. § 360h(b), it did not invoke that authority. For the thousands of Americans implanted with the valve, several hundred of whom had died when the valves broke, *see Bowling v. Pfizer*, 143 F.R.D. 141, 147 (S.D. Ohio 1992), state law afforded the only remedy.

Under Petitioner's and the Government's new formulation of conflict preemption, because the juries in the numerous C/C valve product liability cases might reach different verdicts as to whether the valve had a design defect, whether Shiley had inadequately warned patients of the risks of the valve, and whether Shiley's conduct warranted punitive damages, all of the patients' lawsuits against Shiley should have been impliedly preempted. Under this theory, because the FDA had approved Shiley's premarket approval application, because the FDCA authorized the agency to seek remedies that did not include compensatory damages, *and/or* because the FDCA gave the choice of regulatory remedies to the FDA alone, none of the claims for compensation for deaths caused by the C/C valve could have gone forward. Moreover, their theory would support preemption even in cases where the agency had made express findings of wrongdoing or withdrawn marketing

approval. Tellingly, although in several cases Shiley argued for express preemption, *see, e.g.*, *Michael v. Shiley*, 46 F.3d 1316, the FDA did not file an amicus brief in a single one of the C/C valve cases to suggest that allowing the state-law claims to go forward would interfere with the agency's interests. The United States did, however, file amicus briefs arguing against express preemption in several cases involving medical devices. *See, e.g.*, Brief for United States as Amicus Curiae in *Smith Industries Medical Systems v. Kernats*, S. Ct. No. 96-1405; Brief for United States as Amicus Curiae in *Medtronic v. Lohr*, S. Ct. No. 95-754, 1996 WL 118035; Brief for the Food and Drug Administration as Amicus Curiae in *Duvall v. Bristol-Myers Squibb Co.*, No. 94-1520 (4th Cir.) (dated Mar. 1995); Brief for United States as Amicus Curiae in *Talbott v. Bard*, No. 94-1951 (1st Cir.) (dated Nov. 1994).

Thus, as this Court stated with regard to the scope of express preemption of medical device claims, the Government's justifications for conflict preemption in the circumstances presented here would "have the perverse effect of granting complete immunity to an entire industry that, in the judgment of Congress, needed more stringent regulation" to protect patients. *Medtronic*, 518 U.S. at 487 (opinion of Stevens, J.). Notwithstanding that the Government's intention is narrow, its rationale, broadly applied, risks immunizing not just the medical device industry but manufacturers of drugs and other regulated products as well.

2. Petitioner and the United States also characterize the purported conflict as one with the FDA's market clearance decision. Petitioner, for example, suggests that Respondent's fraud claim infringes on the FDA's authority "to decide whether a device is substantially equivalent to a pre-1976 device and to respond to fraud or misrepresentation in the clearance process." Pet Br. 36. The claim, however, does not challenge the FDA's

decision that AcroMed's screws were substantially equivalent to a pre-1976 device marketed for use in the long bones. The factual issue is whether the intended use stated in the marketing application submitted to the FDA—for fixation of long bones—was the true intended use. Thus, the question of whether Petitioner made misrepresentations does not depend on examination of the FDA's decisionmaking. Furthermore, Respondent's complaint alleges that, just prior to submission of the "fraudulent" marketing application, the FDA had rejected applications for clearance of the true intended use—for fixation of the pedicles of the spine. JA 13-14. Indeed, as Petitioner points out, Pet. Br. 9, when the FDA finally cleared the component parts of the screws for use in the long bones, it required AcroMed "to warn that it had 'NOT BEEN APPROVED FOR PEDICULAR APPLICATION.'" *Id.* (citing JA 19); *see also* JA 124 (1991 letter from FDA to AcroMed stating that promotion of screws for use in pedicles violates FDCA because such use requires premarket approval). Accordingly, the question of whether the application would have been approved had Petitioner not misrepresented the intended use is not a matter of second-guessing the FDA since the FDA itself answered that question in the affirmative more than once.

Petitioner argues that, although the FDA rejected premarket clearance applications for spinal use of the screws in the mid-1980s, to allow patients a remedy for the fraud today would be inconsistent with the FDA's decision in 1998 (and in 1995 with respect to one particular screw intended for one particular use), to allow the devices to be marketed for use in the spine. Pet. Br. 39; *see* 63 Fed. Reg. 40025, 40032 (1998). However, the subsequent marketing clearance came a decade after the alleged fraud. The FDA's decision in 1998 to grant marketing clearance for use in the spine as treatment for certain conditions was not (and, contrary to Petitioner's suggestion, did

not purport to be) a determination whether Petitioner's 1985 application misrepresented the product's intended use. *See* US Br. on Cert. 14. Petitioner is correct that the FDA's 1998 rulemaking concluded that the screws should remain on the market. That fact may be relevant on the issues of causation and damages. For example, Petitioner could argue to a jury that the 1998 clearance granted to some pedicle screw systems to treat specific conditions demonstrates that those devices were worthy of being marketed for those conditions in 1986, notwithstanding Petitioner's misrepresentations, and that the misrepresentations therefore did not harm patients. However, Respondent's complaint does not address whether the screws should be on the market today; the only remedy sought is damages. The claim is therefore not inconsistent with the FDA's 1998 action.

For this and other reasons, *Chicago & North Western Transportation Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311 (1981), is not on point here. In *Kalo Brick*, the petitioner had sought and obtained permission from the Interstate Commerce Commission ("ICC") to stop rail service on a certain line. When the service stopped, the respondent sued the petitioner for damages resulting from the cessation of service. This Court held that the lawsuit was preempted because it required the state court to evaluate the reasonableness of closing the line, an evaluation Congress had assigned to the ICC. The Court pointed out that the Interstate Commerce Act offered administrative remedies but that the respondent had not availed itself of those remedies. Although the Act did not offer a private damages remedy, the available administrative remedies would have allowed the respondent to object to and seek reversal of the agency decision allowing cessation of service.

In contrast, here, Respondent had no administrative remedies to pursue. The only administrative avenue available

—petitioning the FDA to remove AcroMed's screws from the market—would not help already-injured patients. Furthermore, unlike the situation in *Kalo Brick*, when the FDA cleared the screws for marketing in 1986, many patients who later received the pedicle screws would not even have known that they would some day need back surgery. In addition, the claim in *Kalo Brick* did not involve fraud. Here, the nature of the claim is such that Respondent's clients did not know of the problem and suffered no injury until after the FDA granted marketing clearance, AcroMed began promoting its screws solely for an unapproved use, and the individuals represented by Respondent were implanted with and harmed by the pedicle screws. Moreover, *Kalo Brick* left open the question whether a state-law claim would be preempted if the agency were empowered to rule on an issue but had not done so. *Id.* at 327 ("But we need not decide whether a state-court suit is barred when the Commission is empowered to rule on the underlying issues, because here the Commission has actually addressed the matters respondent wishes to raise in state court."). Here, of course, the FDA has not ruled whether its 1986 decision would have been different had Petitioner not misrepresented the devices' intended use, nor does it seem at all likely ever to do so. *See* US Br. on Cert. 14. Finally, as discussed above, the FDA's prior rejection of two applications for the devices at issue when offered for use in the pedicles suggests that a damages action is consistent with the agency's 1986 view. *See supra* p. 16.

The United States also relies heavily on *Arkansas Louisiana Gas Co. v. Hall*, 453 U.S. 571 (1981). That case is inapposite. An award of damages in that case would have effectively afforded the plaintiff a retroactive change in a filed rate for natural gas. However, the Natural Gas Act authorized only the Federal Power Commission to change rates and prohibited even the Commission from doing so retroactively.

On this basis, the damages suit was held to conflict with the Act. In contrast, the FDCA does not concern economic regulation of the drug and medical device industries. Whereas in *Arkla* the remedy sought would have had an effect forbidden under the federal statute (retroactive change in rates), here the remedy sought (damages for personal injury) would have no effect on the matters regulated under the FDCA.

3. Petitioner and the United States also contend that Respondent's claim is preempted because to litigate such claims might involve the FDA in litigation discovery. *See* Pet. Br. 44; U.S. Br. 28. Under this Court's preemption jurisprudence, however, the possibility that private parties would seek discovery from the FDA or FDA officials is not a ground for finding preemption of tort claims. Although both Petitioner's and the Government's briefs attempt to tie this argument to undesirable "practical consequences," neither make any effort to tie the argument to preemption principles or case law. The question whether some other principle of law is implicated by attempts to depose agency officials is not presented here. *See, e.g., United States ex rel. Touhy v. Ragen*, 340 U.S. 462 (1951).

Moreover, the facts of this case belie Petitioner's and the Government's discovery argument. In the MDL court, Respondent did seek discovery from the FDA. However, since the district court dismissed the fraud-on-the-FDA claims against Petitioner and other defendants on preemption grounds early in the litigation, none of that discovery can reasonably be attributed to the claim at issue here. Petitioner's list of discovery allowed by the Court, Pet. Br. 44-45, is thus misleading in that it suggests that the discovery was taken in connection within the fraud-on-the-FDA claim asserted against it. In fact, to our understanding, much of the discovery was sought in response to *defendant* AcroMed's attempt to use the FDA's marketing clearance as a state-law defense. These facts

underscore the breadth of the implied preemption argument urged by Petitioner and its amici here since the discovery related to other types of product liability claims and to other defendants. These facts further show that if the discovery argument supports a finding of implied preemption here, it likewise supports implied preemption of many sorts of traditional state-law product liability claims.

II. THE IDIOSYNCRATIC NATURE OF RESPONDENT'S FRAUD-ON-THE-FDA CLAIM UNDERSCORES THE NARROWNESS OF THE QUESTION PRESENTED.

Although some of the arguments made by Petitioner and the United States are very broad, this case in fact presents a very narrow legal question. This Court's resolution of the preemption issue should affect very few, if any, future cases.

The fraud-on-the-FDA theory is before this Court only because of the presence of an unusual defendant, Buckman, who acted as an agent for the principal defendant, AcroMed. As AcroMed's consultant, Buckman did not have any contact with bone screw patients or their doctors. Therefore, ordinary tort claims for design and manufacturing defects, failure to warn, and common-law fraud against the product manufacturer—such as those brought against AcroMed and later resolved in a class action settlement, *see In re Orthopedic Bone Screw Product Liability Litigation*, 176 F.R.D. 158 (E.D. Pa. 1997)—could not be brought against Petitioner. The *only* theory of liability against Petitioner necessarily centers around Petitioner's interactions with AcroMed and the FDA.

In an ordinary product liability case, however, even if a fraud-on-the-FDA claim were asserted against a drug and device manufacturer, the lawsuit would not center on that

claim. In such a case, the fraud-on-the-FDA claim has no practical importance because the measure of damages relating to the plaintiff's injuries from the device is the same under ordinary tort claims, which are therefore sufficient in themselves to make the plaintiff whole. In addition, the fraud-on-the-FDA claim may well be more difficult to prove than typical tort claims because it may involve agency information that is difficult to obtain. *See United States ex rel. Touhy,* 340 U.S. 462. Thus, as a practical matter, a fraud-on-the-FDA theory will only have potential relevance in the highly unusual context presented here, where the defendant is a manufacturer's agent who deals only with the manufacturer and the FDA, not with doctors and patients.

The practical insignificance of this case is demonstrated by the briefs filed by Petitioner, which, rather than focusing on the case as properly framed, beseech this Court to resolve issues that are not presented by the ruling below or by the facts of this case. Thus, Petitioner has urged this Court to address issues not in the case, Pet. for Cert. at I (two questions presented, which this Court narrowed and re-drafted as one), to overrule *Medtronic* on matters unrelated to the question presented, Pet. Br. 45-50, and to extend its ruling to agencies other than the FDA, *id.* at 39-40, which have very different regulatory structures under vastly different governing statutes. What Petitioner does not do, presumably because it cannot, is point to a single case in which a medical device or drug manufacturer has been held liable by a judge or jury on a fraud-on-the-FDA theory, such as that asserted against Buckman. Thus, Petitioner has completely failed to support its assertion that this claim threatens to "Interfere Substantially With Federal Government Operations." *Id.* at 40.

Indeed, even as to a "consultant" defendant such as Petitioner, the practical effect of the fraud-on-the-FDA theory

would be minimal, if not non-existent. Fraud-on-the-FDA claims against agents inevitably will spur claims for indemnity against the principal tortfeasor/manufacturer, on the ground that it was the manufacturer that harmed the plaintiffs by marketing a device that was defective or not accompanied by appropriate warnings. In the end, fraud-on-the-FDA claims against consultants such as Buckman will fall back on ordinary common-law theories of liability against principals such as AcroMed, which underscores the extremely narrow nature of the question presented.

One additional factor counsels against a broad preemption ruling here. The contours of the state cause of action for "fraud-on-the-FDA" are sufficiently unclear as to give this Court pause about exactly what Petitioner is asking it to find preempted. To be sure, the complaint sets forth various facts that Respondent claims should give rise to liability on a fraud-on-the-FDA theory. JA 13-21. However, the only arguably relevant general statement of law involving the significance of deceptive submissions to a regulatory agency does not recognize a fraud-on-the-agency cause of action, either generally or as against a non-manufacturer agent such as Respondent. *See Restatement (Third) of Torts: Products Liability* § 4, comment e (Amer. Law Inst. 1998). Rather, the Restatement makes the unremarkable point that when a manufacturer defendant provides false or misleading information to a regulatory agency in an ordinary design-defect or failure-to-warn case, the manufacturer's reliance on the state-law defense of regulatory compliance "is entitled to little or no weight." *Id.*

In sum, a ruling from this Court on the case actually before it, rather than the case Petitioner wishes were here, will affect few if any product liability cases. That fact may be a reason to dismiss the writ of certiorari as improvidently

granted. At the very least, it is reason to approach this case very narrowly and rule only on the precise issue before the Court, leaving broader preemption issues for another day.

CONCLUSION

For the foregoing reasons, the judgment of the court of appeals should be affirmed.

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IN THE

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v.

PLAINTIFFS' LEGAL COMMITTEE,

Respondent.

On Writ Of Certiorari To The United States Court Of Appeals For The Third Circuit

AMICUS CURIAE BRIEF OF THE ASSOCIATION OF TRIAL LAWYERS OF AMERICA IN SUPPORT OF THE RESPONDENT

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OTHER AUTHORITIES

Robert S. Adler and Richard A. Mann, *Preemption and Medical Devices: The Courts Run Amok*, 59 Mo. L. Rev. 895 (1994).....17

Fowler V. Harper, Fleming James, Jr., and Oscar S. Gray, THE LAW OF TORTS (2d ed. 1986).....10

Hearings on S. 1944 Before a Subcommittee of the Committee on Commerce, U.S. Senate, 73rd Cong., 2d Sess. 400 (1933).....20

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Restatement (Second) of Torts §310 (1965).....10

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Staff of House Committee on Energy & Commerce, *The Bjork-Shiley Heart Valve: "Earn As You Learn,"* 101 Cong., 2d Sess. (Comm. Print 101-R, 1990) 17

Subcommittee on Oversight and Investigations, House Committee on Energy & Commerce, *Less Than the Sum of its Parts: Reforms Needed in the Organization, Management, and Resources of the FDA's Center for Devices and Radiological Health*, 103d Cong., 1st Sess. (Comm. Print 103-N, May 1993);..... 17

U.S. General Accounting Office, Comptroller General, *Federal Regulation of Medical Devices: Problems Still To Be Overcome* (1993). 18

U.S. General Accounting Office, *Medical Devices: Early Warning of Problems is Hampered by Severe Underreporting* (1986)..... 18

Kenneth J. Witzel, Comment, Medtronic, Inc. v. Lohr *and the Power of Preemption: A Pennsylvania Guide To the Preemption of Common Law Tort Claims by the Medical Device Amendments of 1976*, 102 Dick. L. Rev. 865 (1998) 22

Mitchell Zuckoff & John H. Kennedy, "Heart Catheter Became Killer: Mass.-Made Unit Blamed in Fraud," *Boston Globe*, Oct. 31, 1993 22

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AMICUS CURIAE BRIEF OF THE ASSOCIATION OF TRIAL LAWYERS OF AMERICA IN SUPPORT OF THE RESPONDENT

IDENTITY AND INTEREST OF *AMICUS CURIAE*

The Association of Trial Lawyers of America ("ATLA") respectfully submits this brief as amicus curiae in this case. Letters from Petitioner and Respondent granting blanket consent to the filing of *amicus curiae* briefs have been filed with this Court.[1]

[1] Pursuant to Rule 37.6, Amicus discloses that no counsel for a party authored any part of this brief, nor did any person or entity other than Amicus Curiae, its members, or its counsel make a monetary contribution to the preparation or submission of this brief.

ATLA is a voluntary national bar association whose approximately 50,000 trial lawyer members primarily represent individual plaintiffs in civil actions, including actions seeking damages for wrongful death and personal injury, vindication of civil rights protected under federal and state statutes, and in other actions seeking legal redress.

ATLA is concerned that the broad scope of implied preemption sought by Petitioner and supporting *amici* in this case seriously undermines the fundamental right to seek legal redress for wrongful harm. Elimination of state law remedies in the absence of clearly expressed intent by Congress not only diminishes fundamental right of Americans to access to the courts, but undermines the healthy federalism that is the hallmark of our justice system.

SUMMARY OF THE ARGUMENT

ATLA strongly disagrees with the position advanced by the United States as Amicus Curiae that plaintiffs' cause of action is impliedly preempted by federal law.

I. The intent of Congress remains the ultimate touchstone of preemption analysis, including assertions of implied preemption. The Solicitor General argues that permitting plaintiffs to recover damages for the harm caused by violation of that duty under state law presents a "fatal conflict" with the federal regulatory scheme. In short, the Solicitor General's position is that federal law does not preempt the state law duties or requirements on which plaintiffs base their claims, but impliedly preempts state remedies for their violation.

In ATLA's view, the Solicitor General overstates the duty not to deceive federal agencies as among the unique federal interests that require the displacement of state law. Although federal agencies undoubtedly have a strong interest in the truthfulness and reliability of the information

submitted to them, this is not a uniquely national interest. By basing preemption of state law on any federal interest that can be characterized as important, the Solicitor General treats the intent of Congress, as reflected in the provisions of the statute, as inessential.

At the same time, the Solicitor General undervalues the interests of the states in affording legal redress for physical injury caused by tortious misconduct. The fraud cause of action alleged by plaintiffs tracks the well-settled tort of liability for physical harm caused by intentional misrepresentation to a third party. Although the third party in this instance is the FDA, misrepresentation to a governmental agency is not an essential element of the tort.

Moreover, the interest protected by this common law tort is not the interest of the third party not to be deceived. It is the interest of those who foreseeably may be physically harmed as a result of the misrepresentation. The protection of health and safety by awarding damages for harm caused by tortious conduct is an area that has traditionally been occupied by state law.

II. The Solicitor General argues that three types of conflict with the federal regulatory scheme result from allowing plaintiffs' state law cause of action for physical injury resulting from misrepresentations to the FDA: That state remedies undermine the FDA's exclusive authority in enforcing requirements for truthful disclosures, that they conflict with FDA's decision to grant market clearance, and that they may impose on the FDA burdensome entanglements in private litigation.

ATLA submits that none of these concerns present a significant conflict with Congress's purposes and objectives as reflected in the express provisions of the MDA. Indeed, the statutory provisions reflect a regime in which state remedies supplement federal enforcement. The absence of a federal private cause of action argues in favor of the

preservation of state remedies. The speculative burden on the FDA may support steps to ensure the agency's efficient operation, but does not support interference with the states' authority within our system of federalism to provide legal redress for wrongful injury to its citizens.

ARGUMENT

I. PLAINTIFFS' STATE TORT ACTION FOR PERSONAL INJURIES RESULTING FROM FRAUD OR MISREPRESENTATION DOES NOT INTRUDE ON UNIQUELY NATIONAL INTERESTS, BUT PROTECTS HEALTH AND SAFETY, A FIELD TRADITIONALLY OCCUPIED BY STATE LAW.

Plaintiffs in this case are people who suffered physical harm allegedly caused by pedicle screws used in spinal surgical procedures. They allege that they were exposed to this danger as a result of defendant's conscious misrepresentations to the Food and Drug Administration in obtaining approval to market the devices.

The lower courts have not yet ruled that plaintiffs' claim states a valid cause of action under state law or that plaintiffs' evidence is sufficient on each of the essential elements. *See* 159 F.3d 817, 829 (3d Cir. 1998). For this reason, ATLA views much of Petitioner's discussion of the appropriate interpretation of the company's representations of "intended use" as not directly responsive to the limited Question Presented.

ATLA agrees with the position stated in the Brief of the United States as Amicus Curiae that plaintiffs' state law cause of action is not expressly preempted by the Medical Device Amendments of 1967 to the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360k(a). The Solicitor General correctly states that plaintiffs' "common law theory of liability does not rest on the imposition of a duty that is

'different from' or 'in addition to' federal requirements. Instead, that common law theory is consistent with the duties imposed by applicable federal requirements." [U.S. Br. at 19-20]

ATLA, however, strongly disagrees with Part II of the Brief of the United States, which argues that permitting plaintiffs to recover damages for the harm caused by violation of that duty under state law presents a "fatal conflict" with the federal regulatory scheme. In short, the Solicitor General's position is that federal law does not preempt the state law duties or requirements on which plaintiffs base their claims, but impliedly preempts state remedies for their violation.

In ATLA's view, the Solicitor General overstates the duty not to deceive federal agencies as among the "unique federal interests that require the displacement of state law." U.S. Br. at 23. At the same time, the Solicitor General undervalues the interests of the states in affording legal redress for physical injury caused by tortious misconduct. The protection of health and safety by awarding damages for harm caused by tortious conduct is an area that has traditionally been occupied by state law.

A. Remedies for Harms Resulting from Misrepresentation to Federal Agencies Are Not A Matter of Such Uniquely National Concern that Congress May Be Presumed to Intend Preemption.

The intent of Congress remains "the ultimate touchstone in every pre-emption case." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996). It is no less essential in implied preemption cases, where the Court has recognized three bases for superseding state law.

> If Congress has not entirely displaced state regulation over the matter in question, state law is still pre-empted to the extent it actually conflicts with federal

> law, that is, when it is impossible to comply with both state and federal law, or where the state law stands as an obstacle to the accomplishment of the full purposes and objectives of Congress.

Silkwood v. Kerr-McGee Corp., 464 U.S. 238, 248 (1984). Regardless of the type of implied preemption asserted, the "ultimate question in each case, as we have framed the inquiry, is one of Congress's intent, as revealed by the text, structure, purposes, and subject matter of the statutes involved." *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 545 (1992) (Scalia, J. dissenting).

In instances of "field" preemption and "impossibility" preemption, congressional intent to supersede conflicting state law can reasonably be inferred. However, this is not a case in which Congress has made clear its intent to preempt the entire field of regulation, leaving no room for state law to supplement it. *Cf. United States v. Locke*, 120 S. Ct. 1135 (2000). Indeed, the Court in Medtronic held that the Medical Device Amendments expressly provide for a role for state regulation and state causes of action for compensation. Nor is compliance with state and federal duties not to deceive impossible, since they are consistent. [U.S. Br. at 19-20]

Rather, the Solicitor General asserts, permitting the state law damages remedy sought by plaintiffs raises the possibility of a conflict with federal interests.

Hines v. Davidowitz, 312 U.S. 52 (1941), established the principle of implied preemption of state law that "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." This Court held that Pennsylvania's Alien Registration Act must yield in the face of uniquely national interest. Justice Black emphasized that "it is of importance that this legislation is in a field which affects international relations, the one aspect of our government that from the first has been most generally conceded imperatively to demand broad national authority.

Any concurrent state power that may exist is restricted to the narrowest of limits." 312 U.S. at 67-68.

Implicit in *Hines* is the notion that the fact that a state law intrudes in a field that is intrinsically national, and in which the states powers are necessarily limited, can serve as a proxy for congressional intent that the state law must yield. As the Court later explained, in a case involving local regulation of blood plasma:

> [I]n the seminal case of *Hines v. Davidowitz*, [312 U.S. 52 (1941)], the Court inferred an intent to preempt from the dominance of the federal interest in foreign affairs because 'the supremacy of the national power in the general field of foreign affairs . . . is made clear by the Constitution,' . . . and the regulation of that field is intimately blended and intertwined with responsibilities of national government. Needless to say, those factors are absent here. Rather, as we have stated, the regulation of health and safety matters is primarily and historically, a matter of local concern.

Hillsborough County v. Automated Medical Laboratories, Inc., 471 U.S. 707, 719 (1985)

Curiously, the Solicitor General does not cite *Hines*, instead relying most heavily on *Boyle v. United Technologies Corp.*, 487 U.S. 500 (1988). In that case, plaintiff sought recovery for wrongful death against the manufacturer of a military helicopter which crashed. The Court determined that plaintiff's state product liability claim would impose a duty that conflicted with the requirements in defendant's contract with the United States government. The Court therefore held that state law was trumped by a federal government contractor defense fashioned by the Court, in the absence of a statutory provision, as a matter of federal common law.

Extending *Boyle's* judicial preemption to this case, where Congress has provided a regulatory statute -- which includes an express preemption provision -- makes the intent of Congress, as reflected in the text and purposes of the statute, nonessential.

The Solicitor General would extend the breadth of this new preemption even further. The Court in *Boyle* repeatedly emphasized that the scope of its decision was narrow, limited it to situations in which there is a "significant conflict" between state law and matters of "uniquely national interest." *Id.* at 507. The Solicitor General quickly casts aside that limiting principle in favor of interests that may be important to federal agencies, but are not uniquely national.

Undoubtedly, it is important that agencies receive accurate and truthful information from regulated entities. But deceit is not uniquely national. Moreover, given the myriad activities requiring federal approvals or licenses, the impact of misrepresentation extends far beyond the federal government. For example, if a company fraudulently procures a patent which it uses to entice investors, those who suffer losses are in no different position than the victims of misrepresentations made to a state agency or private party. *Cf. Belmac Hygiene, Inc. v. Belmac Corp.*, 121 F.3d 835 (2d Cir. 1997)(under Florida law, defendant could be liable to corporate investor based on partner's misrepresentation to FDA concerning the testing of a contraceptive which defendant used to persuade plaintiff to invest in the venture.)

Federal law, of course, must govern the reporting and disclosure obligations of entities regulated by federal agencies. However, where state law imposes no different or additional duty, no "significant conflict" with uniquely national interests arises from permitting a compensatory remedy. As the plurality stated in *Cipollone*, there is "no general, inherent conflict between federal preemption of state

warning *requirements* and the continued vitality of state common law damages actions," 505 U.S. at 518.

Even in a field of such overriding national interest as safety regulation of nuclear power, this Court found no inconsistency between "vest[ing] the NRC with exclusive regulatory authority over the safety aspects of nuclear development while at the same time allowing plaintiffs like Mr. Silkwood to recover for injuries caused by nuclear hazards." *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 258 (1984). On this point, the dissent agreed. "Compensatory damages therefore complement the federal regulatory standards, and are an implicit part of the federal regulatory scheme." *Id.* at 264 (Blackmun, J., dissenting).

Cut loose from its anchor in the intent of Congress, the theory of preemption proposed by the Solicitor General "invites an unelected federal judiciary to make decisions about which state policies it favors and which ones it dislikes." *Garcia v. San Antonio Metropolitan Transit Auth.*, 469 U.S. 528, 546 (1985). In doing so it tramples on important principles of federalism.

B. The Cause of Action for Physical Harm Resulting From Misrepresentation Is A Traditional Tort Within the Historic Role of the States.

This Court in *Medtronic* reaffirmed the strong presumption against preemption when Congress legislates in a field that state law has traditionally occupied, particularly in matters affecting health and safety. 518 U.S. at 485. Acknowledging this longstanding principle, U.S. Br. at 17, the Solicitor General would nonetheless cast it aside in this instance.

The Solicitor General takes the position that plaintiffs' is not a traditional product liability claim, but rather a "newly fashioned state-law tort of committing fraud on a federal regulatory agency." U.S. Br. at 18. Consequently, the Solicitor General argues, plaintiffs' cause

of action is not within an area traditionally occupied by the states and would not even exist but for the federal statute involved. It is an area governed entirely by federal law concerning the relationship between federal agencies and regulated entities, where the states have no legitimate role. *Id.*

The Solicitor General insists upon characterizing this tort as "fraud on the FDA" as if the federal agency were an essential element of the tort. Count I in Plaintiffs' sample complaint is entitled "Fraud (on the FDA)." The parentheses clearly distinguish this allegation of fraud accomplished by intentional misrepresentation to a third party (here the FDA), from alleged misrepresentations made directly to doctors and patients.

The Solicitor General misunderstands the nature and history of this cause of action. From at least the end of the 18th Century, common law courts imposed liability on one who makes an intentional misrepresentation to a third party, inducing justifiable reliance which results in harm to the plaintiff. 2 Fowler V. Harper, Fleming James, Jr., and Oscar S. Gray, THE LAW OF TORTS § 7.1 (2d ed. 1986). Liability extended to one who makes misrepresentations contained in documents required by statute to be filed with a government agency. *Id.* at § 7.2; Restatement of Torts (Second) § 536 (1977).

This basis of liability was reflected in Restatement (First) of Torts § 310 (1938), and was incorporated, with some change in wording, in Restatement (Second) of Torts §310 (1965). That section provides:

> An actor who makes a misrepresentation is subject to liability to another for physical harm which results from an act done by ... a third person in reliance upon the truth of the representation, if the actor
> (a) intends his statement to induce or should realize that it is likely to induce action by ... a third person, which involves an unreasonable risk of physical harm to the other, and
> (b) knows
> (i) that the statement is false, or
> (ii) that he has not the knowledge which he professes.

It is most important to note that, although the misrepresentation is made to a third party, the tort does not exist to protect that party's interest in not being deceived. Rather, "liability is based upon the unreasonable risk of physical harm which is involved in the misrepresentations, and not upon the fact that the misrepresentations are intended to mislead." *Id.* comment a.

There are relatively few reported cases applying section 310 to liability for product related injuries for the obvious reason that it is generally far easier to establish strict liability and misrepresentation under 402A and 402B. For this reason, the dire warnings of massive liability that would follow upon a ruling against preemption are suspect.

II. PLAINTIFFS' STATE LAW REMEDIES FOR FRAUD BASED ON MISREPRESENTATIONS TO THE FDA PRESENT NO SIGNIFICANT CONFLICT WITH THE FEDERAL REGULATORY SCHEME.

The Court in *Boyle* emphasized that a unique federal interest is a necessary, but not sufficient basis for displacing state law. There must also be a "significant conflict" with federal law. 487 U.S. at 507-08. The Solicitor General suggests three bases for eliminating plaintiffs' state law cause of action for physical injury resulting from misrepresentations to the FDA: state remedies undermine the FDA's exclusive authority in enforcing requirements for truthful disclosures; they conflict with FDA's decision to

grant market clearance; and they may impose on the FDA burdensome entanglements in private litigation.

ATLA submits that none of these concerns present a significant conflict with Congress's purposes and objectives as reflected in the express provisions of the MDA. Indeed, the statutory provisions reflect a regime in which state remedies supplement federal enforcement. The absence of a federal private cause of action argues in favor of the preservation of state remedies. The speculative burden on the FDA may support steps to ensure the agency's efficient operation, but does not support interference with the states' authority to provide legal redress for wrongful injury to their citizens.

In sum, the arguments represent an example of "seeking out conflicts between state and federal regulation where none clearly exists." *English v. General Electric Co.*, 496 U.S. 72, 81, 90 (1990), quoting *Huron Portland Cement Co. v. City of Detroit*, 362 U.S. 440, 446 (1960)

A. Congress's Regulatory Scheme Does Not Require Exclusive FDA Control To the Exclusion of State Remedies to Compensate the Victims of Fraud or Misrepresentation

1. The Express Provisions of the Medical Device Amendments Establish A Regime In Which State Remedies Supplement FDA Enforcement.

The Solicitor General's primary argument in favor of denying plaintiffs the right to seek compensation under state law is that, even when state law does not impose different or additional *requirements,* permitting a compensatory *remedy* outside the agency's control conflicts with the FDA's exclusive authority to determine whether it has been defrauded and what penalty, if any to exact. U.S. Br. at 21.

This Court in *Medtronic* discerned no such conflict:

> Nothing in § 360k denies Florida the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements. . . . The presence of a damages remedy does not amount to the additional or different "requirement" that is necessary under the statute; rather, it merely provides another reason for manufacturers to comply with identical existing "requirements" under federal law.

518 U.S. at 495.

The dissenting Justices were of the same view:

> Where a state cause of action seeks to enforce an FDCA requirement, that claim does not impose a requirement that is "different from, or in addition to" requirements under federal law. To be sure, the threat of a damages remedy will give manufacturers an additional cause to comply, but the requirements imposed on them under state and federal law do not differ. Section 360k does not preclude States from imposing different or additional remedies, but only different or additional requirements.

Id. at 513 (O'Connor, J., dissenting in part).

Although the Court's primary focus in *Medtronic* was the MDA's express preemption provision, it is surely unlikely that a conflict of the significance described by the Solicitor General would have escaped all notice.

Moreover, the enforcement provisions which Congress adopted in the MDA do not exclude state remedies, but clearly establish a regime in which FDA enforcement and state remedies are supplementary.

For example, 21 U.S.C. § 360g makes provision for judicial review of the variety of regulations and orders (or the modification or revocation of regulations or orders) issued under sections 360c, 360d, 360e, 360f, 360h, 360i, 360j, or 360k. Congress explicitly provided in Section 360g(e): "The remedies provided for in this section shall be in addition to and not in lieu of any other remedies provided by law."

Even more instructive is the regime Congress has established in § 360h for enforcement of orders to repair or replace unreasonably dangerous devices and reimburse the patient or buyer for all the expenses actually incurred.

As originally proposed, the section vested sole discretion for making these determinations and ordering the appropriate remedies in the FDA. In testimony before the Senate Subcommittee on Health of the Committee on Labor and Public Welfare, representatives of the device and pharmaceutical makers voiced their concerns with the provision as drafted. They were particularly concerned with the allocation of exclusive authority to the FDA, to the exclusion of state product liability court actions where they had enjoyed success in defending their products.

Foster Whitlock, vice-chairman of Johnson & Johnson's board of directors and chairman of the Pharmaceutical Manufacturers Association, stated that S. 2368 § 515(c) (the original draft of §360h) "will result in a substantial and significant change in the traditional legal approach to the handling of product liability matters. . . This provision does not provide the manufacturer with a hearing before the determination is made to require these remedies. Nor does it expressly give the manufacturer a choice of remedies." Hearings before the Subcommittee on Health of the Committee on Labor and Public Welfare, U.S. Senate, 93rd Cong., 1st Sess. pp. 463-64 (1975).

Kenneth A. Marshall, representing the Health Industries Association, stated that "Replacement or

reimbursement are matters which should not be left to the secretary . . . the question of whether a product is defective is ultimately decided by a jury." *Id.* at 477.

C. Joseph Stetler, president of the Pharmaceutical Manufacturers Association, testified:

> We agree that manufacturers should be liable for defective products as is the case under the law today. The provision would result in a substantial and significant change in the traditional legal approach to the handling of product liability matters. It could eventually replace the current court-adjudication system in liability in individual cases with an administrative class-action approach.

Id. at 362.

In response to these concerns, Congress modified § 360h in a number of respects. Provision was made for consultation and informal hearings with manufacturers. Most significantly, Congress added § 360h(d) to make clear that it was not eliminating common law product liability actions. That section provides:

(d) Effect on other liability

> Compliance with an order issued under this section shall not relieve any person from liability under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy provided him under such order shall be taken into account.

Congress not only contemplated that state damage lawsuits would continue after enactment of the MDA, but it took pains to address any potential conflict with FDA enforcement by harmonizing the recoverable damages to

avoid double recovery by plaintiffs. *See also Mulligan v. Pfizer,* 850 F. Supp. 633, 636 (S.D. Ohio 1994)(holding that § 360h(d) reflects congressional intent to preserve state tort claims).

2. Preemption of State Remedies Would Undermine Purposes and Objectives of Congress.

By definition, misrepresentation and fraud are intended to deceive the FDA. To rely solely on the FDA to determine whether it has been defrauded and impose the only sanction would appear to be an extraordinary vote of confidence in the power and ability of the agency to police a very large industry without any additional assistance from the states.

In reality, state law product liability lawsuits have made an important contribution to achieving Congress's purpose of ensuring the safety of medical devices marketed to the public. Nowhere has this contribution been more important than in those instances where companies have been guilty of misrepresentation or failure to disclose serious dangers in medical devices. One need look no further than the experience with the Dalkon Shield, a device which inflicted harm on thousands of women, prompting a large number of lawsuits and providing the impetus for passage of the MDA itself. *Medtronic,* 518 U.S. at 476 The story does not support the Solicitor General's insistance that proper regulation of the device industry demands reliance solely on FDA enforcement without the "hindrance" of product liability lawsuits. U.S. Br. at 18.

> Robins' dishonesty regarding the efficacy of its device, its refusal to conduct adequate testing of the Dalkon Shield, its ignoring of numerous adverse reports from physicians, its attacks on the personal character of victims in product liability lawsuits, and, ultimately, its suppression and illegal destruction of damning evidence against it were uncovered only after years of product liability litigation, some of which was unsuccessful because of Robins' suppression of critical evidence. In fact, none of this evidence was sought by, or discovered, by FDA. To the contrary, FDA turned its attention away from the Dalkon Shield after negotiating a "voluntary" suspension of sales in the United States on June 26, 1974. Not until 1984, ten years later, after being publicly castigated by a federal judge overseeing a group of product liability cases, did Robins finally begin a campaign to convince women to have the IUDs removed.

Robert S. Adler and Richard A. Mann, *Preemption and Medical Devices: The Courts Run Amok*, 59 Mo. L. Rev. 895, 944-45 (1994). The authors conclude that "had preemption been applied to the Dalkon Shield, A.H. Robins would have succeeded in operating incompetently and illegally. More importantly, hundreds of thousands of injured women would have been denied recompense and justice. . . . despite its commendable efforts on behalf of the public, FDA simply cannot provide an adequate source of safety to the public from dangerous medical devices. *Id.* at 945 *See generally*, Richard B. Sobol, Bending the Law: THE STORY OF THE DALKON SHIELD BANKRUPTCY, 2-48 (1991).

In fact, Congress has repeatedly identified shortcomings in FDA's regulation of medical devices. *See, e.g.,* Subcommittee on Oversight and Investigations, House Committee on Energy & Commerce, *Less Than the Sum of its Parts: Reforms Needed in the Organization, Management, and Resources of the FDA's Center for Devices and Radiological Health*, 103d Cong., 1st Sess. (Comm. Print 103-N, May 1993); Staff of House Committee on Energy & Commerce, *The Bjork-Shiley Heart Valve: "Earn As You Learn,"* 101 Cong., 2d Sess. (Comm. Print 101-R, 1990); *see*

also U.S. General Accounting Office, *Medical Devices: Early Warning of Problems is Hampered by Severe Underreporting* (1986); U.S. General Accounting Office, Comptroller General, *Federal Regulation of Medical Devices: Problems Still To Be Overcome* (1993).

In sum, the plain language of the Medical Device Amendments demonstrates that Congress intended to preempt different or additional state *requirements*, but intended to preserve state *remedies*. To require that enforcement depend solely upon the sanctions imposed by the FDA, to the exclusion of state law damage remedies for victims, would undermine the objective and purpose of Congress in enacting the MDA.

B. Permitting Plaintiffs' State Law Remedy Is Not Inconsistent With Congress's Decision Not to Provide a Private Federal Cause of Action.

The district court ruled that plaintiff's Count I claim is preempted, reasoning that to allow plaintiffs to pursue their damages remedy under state law conflicts with Congress's decision not to create a private cause of action for damages caused by violation of the Federal Food Drug and Cosmetic Act and the Medical Device Amendments. See 159 F.3d at 825. The Third Circuit reversed, correctly stating that the district court's ruling was "contrary to the clear holding of *Lohr*." *Id.*

Nevertheless, the Solicitor General argues that the absence of a private cause of action is part of a comprehensive regulatory scheme in which the FDA must have "exclusive authority to determine how the provisions of the Act should be enforced." U.S. Br. at 22-23. The Pharmaceutical Research and Manufacturers of America echo this position: "Congress's decision not to create a federal private right of action to enforce the FFDCA and MDA does

not suggest that injured parties should be permitted to seek compensation under *state* law." PRMA Br. at 14.

To the contrary, this Court has long held that state damage remedies are not impliedly preempted where those harmed by tortious conduct would be left without any remedy. As this Court stated in *United Construction Workers v. Laburnum Const. Co.*, 347 U.S. 656, 663-64 (1954).

> Congress has neither provided nor suggested any substitute for the traditional state court procedure for collecting damages for injuries caused by tortious conduct. For us to cut off the injured respondent from this right of recovery will deprive it of its property without recourse or compensation. To do so will, in effect, grant petitioners immunity from liability for their tortious conduct. We see no substantial reason for reaching such a result.

Again, in *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984), the Court refused to deprive injured plaintiffs of state law remedies in the absence of an explicit statement that Congress so intended:

> This silence (of Congress) takes on added significance in light of Congress' failure to provide any federal remedy for persons injured by such conduct. It is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct.

464 U.S. at 251. Justice Blackmun, dissenting in *Silkwood*, nonetheless agreed with the majority that the absence of federal regulation governing the compensation of victims is strong evidence that Congress intended the matter to be left to the States. *Id.* at 264 n.7.

The Court in *Lohr* found this reasoning directly applicable to Medtronic's assertion of preemption under the Medical Device Amendments. In view of the absence of a

private cause of action for damages, the plurality stated, broad preemption of state remedies would "have the perverse effect of granting complete immunity from design defect liability to an entire industry that, in the judgment of Congress, needed more stringent regulation . . . It is, to say the least, 'difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct.'" quoting *Silkwood, supra.*

Indeed, Congress has not been entirely silent with respect to its intent in not providing a private cause of action.

As originally drafted, the FDCA in 1938 included section 25, entitled "Liability for Personal Injuries -- a right of action for damages shall accrue to any person for injury or death proximately caused by a violation of this Act." See H.R. 6110, 73rd Cong., 1st Sess. §25 (1933).

Section 25 of the House proposal, which was section 24 of the Senate version, was "striken from the bill on the ground that it is unnecessary. A common-law right of action exists." Hearings on S. 1944 Before a Subcommittee of the Committee on Commerce, U.S. Senate, 73rd Cong., 2d Sess. 400 (1933). *See also id.* at 431 ("the party injured now has every reasonable protection under the law and a right of action for damages."); *id.* at 403 ("This act should not attempt to modify or restate the common law with respect to personal injuries").

Based on this legislative history, courts have concluded that Congress intended that personal injury actions continue to be available under state tort law. *See Consumer Federation of America v. Upjohn,* 346 A.2d 725, 731 (D.C. App. 1975); *Broward County v. Eli Lilly & Co.*, 329 FS 364, 365 (SD Fla. 1971).

C. Plaintiffs' State Law Damages Remedy Does Not Conflict With FDA Market Clearance Decisions.

The Solicitor General's second basis for seeking implied conflict preemption is that plaintiffs' lawsuit would impose liability for marketing a device that the FDA has expressly approved for marketing, thereby failing to give effect to the FDA's administrative decision. U.S. Br. at 25-26. The Pharmaceutical Manufacturers echo this point, arguing that permitting injured plaintiffs to seek compensation would allow states "through the imposition of massive civil liability, to effectively override the FDA's approval decision."

What the Solicitor General postulates is a false conflict: A situation where plaintiff alleges defendant violated truthful disclosure requirements, but the FDA has decided to grant (or continue) market clearance anyway. Under the very terms of the Solicitor General's hypothetical situation, the defendant cannot be liable under state law because its statement was not the proximate cause of the FDA's decision. Perhaps the agency did not view the statement as false, or did not deem it material, or for some other reason decided that the drug or device should gain access to the market. In any event, the terms of the hypothetical itself negates an essential element of state law liability, that the FDA would not have granted market access but for the defendant's alleged misrepresentation.

In the case before this Court, there is even less of a basis for finding a clear federal-state conflict. At this stage of the proceeding, it is unknown whether plaintiffs have stated a valid cause of action under state law. The Third Circuit took care to state, "We do not hold that plaintiffs have or have not alleged a legally sufficient causal nexus." 159 F.3d at 827. ATLA suggests that the States should not be presumed in advance to violate their obligations under the Supremacy Clause. The Solicitor General's assertion that any state law cause of action will necessarily fail to give effect to the FDA's administrative decision is purely speculative and premature.

ATLA is most concerned that the Solicitor General seeks a blanket preemption that extends beyond the situation where the FDA stands by its market clearance decision to cases where the agency has condemned a company's fraud, ordered the drug or device withdrawn from the market, and imposed punishment on the company and individuals responsible.

That is precisely the situation that was presented in *Talbott v. Bard*, 865 F. Supp. 37 (D. Mass. 1994), aff'd, 63 F.3d 25 (1st Cir. 1995), cert. denied, 116 S. Ct. 1892 (1996). The manufacturer had obtained market clearance under § 510k by fraudulent statements that failed to disclose known failures caused by a life-threatening defect in the catheter. In the wake of a growing number of deaths and injuries, the FDA opened an inquiry. Ultimately, the investigation resulted in C.R. Bard pleading guilty to 391 counts of conspiracy, mail fraud, lying to regulators, and shipping adulterated products. The company was fined $61 million. Three Bard executives convicted of making false statements to the FDA and were sentenced to eighteen months in prison. *See* Kenneth J. Witzel, Comment, Medtronic, Inc. v. Lohr *and the Power of Preemption: A Pennsylvania Guide To the Preemption of Common Law Tort Claims by the Medical Device Amendments of 1976*, 102 Dick. L. Rev. 865, 880-83 (1998); and Mitchell Zuckoff & John H. Kennedy, "Heart Catheter Became Killer: Mass.-Made Unit Blamed in Fraud," *Boston Globe*, Oct. 31, 1993, at 1.

In a wrongful death suit by the family of one victim, the First Circuit held that the claims were barred by the MDA, employing a broad theory of blanket preemption that this Court subsequently rejected in *Medtronic*. With respect to the company's fraudulent statements made to obtain market approval, the court of appeals ruled that permitting the family to recover damages would conflict with the broad authority of the FDA to order the product off the market and initiate criminal prosecutions. The Pharmaceutical

Manufacturers recognize that the broad implied preemption sought in this case would resurrect *Talbott's* broad immunity from liability. PRMA Br. at 13 n.6.

The United States filed a brief as *amicus curiae* in *Talbott*. The Solicitor General explicitly rejected the rationale that the FDA, not a judge or jury, must be accorded exclusive authority to fix the consequences of a company's fraudulent statements:

> The concern raised in Judge Aldrich's opinion is irrelevant to this case. The FDA initially approve the catheter model that allegedly caused Ms. Beavers' death, but on the basis of "allegedly fraudulent, misleading and inaccurate documentation submitted by Bard," J.A. 287-87. The FDA subsequently initiated enforcement actions against Bard and the other defendants. Thus, to the extent that plaintiffs' state-law claims are premised on the FDA's judgment that Bard failed to comply with federal requirements, there is no risk that additional requirements will be imposed in this case by a judge or jury.

Talbott v. Baird, *supra*, Brief for the United States As Amicus Curiae at 25.

ATLA suggests that the Solicitor General "got it right" in *Talbott*, and that the opposite position the Solicitor General now adopts is inconsistent both with the provisions of the statute and its purposes and objectives.

D. Speculative Concerns that State Law Damage Actions Will Result in Undesirable Practical Consequences for the FDA Do Not Warrant Their Preemption.

Finally, the Solicitor General asserts that preemption is necessary to keep the FDA from being burdened and entangled by private lawsuits seeking discovery. U.S. Br. at 28-30.

It does not appear that direct proof of the state of mind of FDA officials is at all necessary to plaintiffs' cause of action. For example, in *Stanton by Brooks v. Astra Pharmaceutical Products*, 718 F.2d 553, 568-69 (3d Cir. 1983) the court held that a patient alleging injury caused by defendant's misleading statements to the FDA produced sufficient evidence of reliance of the part of the FDA through expert testimony.

In any event, as the Solicitor General acknowledges, federal agencies are capable of protecting themselves against overwhelming demands on their personnel made by private parties in litigation. *United States ex rel. Touhy v. Ragen*, 340 U.S. 462 (1951). The Solicitor General complains that some lower courts have taken divergent views concerning the protection of agency personnel. U.S. Br. at 28-29. The Solicitor General's argument is properly addressed to the reviewing authority of this Court. It does not compel eliminating state causes of action on the ground that they may generate more subpoena requests.

Further, courts are authorized to protect nonparties from overly burdensome discovery. Fed. R. Civ. Pro. 26 and 45. Congress, of course, possesses ample authority to provide sufficient resources to federal agencies and to protect them from inappropriate drain on those resources.

As for the speculation that potential liability may prompt regulated entities to submit more information than the FDA desires, U.S. Br. at 30, the Supremacy Clause does not represent a blanket authorization for federal agencies to enlist the assistance of state courts to accomplish their missions.

This Court had recent occasion to recall the explanation by Chief Justice Marshall that the federal government's "means are adequate to its ends; and on those means alone was it expected to rely for the accomplishment of its ends." *McCulloch v. Maryland*, 4 Wheat. 316, 424 (1819), quoted in *Alden v. Maine*, 527 U.S. 706, 753 (1999)

The Court further cautioned, "When Congress legislates in matters affecting the States, it may not treat these sovereign entities as mere prefectures or corporations," but must treat them as "joint participants in the federal system." *Id.* at 758.

CONCLUSION

For the above reasons, the decision of the court of appeals should be affirmed.

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